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13. ABSTRACT (Maximum 200 Words) The feasibility of developing a veteran cohort to evaluate factors that influence prostate cancer incidence was assessed. We identified 80,720 eligible veterans without prostate cancer through VA computerized records for six Medical Centers (VAMC). A lifestyle questionnaire was mailed along with a dietary survey (HFFQ) to 3,000 veterans (500 per site), randomly selected from a file of eligible participants. A phone survey was developed to ascertain reasons for non-response from individuals who didn't participate after two mailing attempts. The response rate overall was 24.4%. Response was lower for African-Americans (19.4%) than Whites (29.4%). Veterans were also recruited through a face-to-face approach at one VAMC. Of 121 eligible veterans, 90% agreed to participate and were handed or mailed surveys to return to us. The overall return rate was 42.6%. Response among Whites was higher (60.0%) than African-Americans (32.4%). Most veterans contacted regarding non-response felt the survey asked too many questions. African-American non-responders were more concerned about confidentiality and reported more difficulties understanding questions. Though survey response was not as high as expected, the VA provides a unique arena to establish observational cohorts for assessing the health of African-American and White men.			
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INTRODUCTION

Prostate cancer is the most common cancer in men. Approximately 180,000 men will receive a diagnosis for prostate cancer and 40,000 men will die from the disease this year.¹ Incidence and mortality rates are higher among African-American men than white men, however the reasons for this increase are not clear.^{2,3} Some studies suggest that dietary factors may be important risk factors for prostate cancer, including high consumption of fats and meat,^{4,5,6} low intake of lycopene (from tomato products),^{7,8} low intake of fruit,⁹ and low intake of dietary calcium. The intent of this study was to evaluate the feasibility of establishing a large observational cohort of African American males and an equal number of white males for the purpose of studying lifestyle, as well as genetic factors that may influence the incidence of prostate cancer. We established a pilot of US Veterans without prostate cancer utilizing the Department of Veteran Affairs (VA) health care system computerized administrative databases. Equal numbers of African-Americans and whites received dietary and lifestyle surveys to obtain information on risk factors that may be associated with prostate cancer (n=3,500). We conducted a follow-up phone survey of veterans who did not respond to the initial mail surveys to determine reasons for non-response.

BODY

A Methods

A.1 Overview – Research Design

This was a prospective, longitudinal, cohort study to identify lifestyle, dietary, and biological factors that may be associated with the risk of prostate cancer among US male veterans, with particular emphasis on ethnic differences between African-Americans and Whites. The study was a pilot project to evaluate the feasibility of establishing such a large cohort of African-American and white veterans for future cohort development. The primary study objectives were:

- 1) To examine the feasibility of establishing a cohort of African-American men with a parallel cohort Caucasian males for study of lifestyle, dietary, and biological determinants of prostate cancer, and
- 2) To identify the opportunities and barriers to establishing observational cohorts of veterans for epidemiological studies.

Using VA Out-Patient (OPC) and In-Patient (PTF) Treatment Files, we established a data file of African-American and White veterans who used VA medical services from October 1997 to June 1999. The sample was selected from six (6) VA Medical Centers that have a high concentration of African-American users. Study participants were mailed questionnaires to collect information on lifestyle behavior, such as smoking, family history of prostate cancer, weight, height, exercise, and diet, as well as medical history and quality of life. Subjects responding to the survey were asked to provide a sample of blood for conducting biological and genetic analyses. Subjects who did not respond to the survey request were contacted by phone to identify barriers to survey response. Response rates to the surveys and ascertainment of questionnaire data are used to evaluate the feasibility of establishing large national cohorts in the VA.

A.2 Sample / Case Selection

A.2.A Data Sources

VA in-patient (PTF) and out-patient (OPC) files were used to identify African-American and white veterans without prostate cancer for recruitment into the cohort. The VA maintains a national database containing information on inpatient and outpatient utilization by veterans who use the VA medical system. The Patient Treatment File (PTF) is a national in-patient abstract database for all VAMCs. The PTF contains patient characteristics such as age, sex, race, marital status, year of discharge, and up to 10 discharge diagnoses, 50 surgical procedures, and 50 diagnostic procedures coded according to the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). The Out-Patient Clinic File (OPC) includes similar patient information, date of out-patient visit, type of clinic visited, and diagnostic and procedure codes. These patient files provide the ability to follow health outcomes of veterans who utilize the healthcare within the VA medical system. In addition, records can be linked to patients' social security numbers allowing mergers to patient information from other data sources thus increasing the versatility of the data files.

A.2.B Selection of Sample

An outline of case selection from OPC and PTF files is provided in Appendix A. First we established a data file of all veterans who utilized VA services from October 1997 to June 1999 at six VA medical centers. The six VA Medical Centers were chosen based on utilization of VA health services by African-Americans. The sites used for recruitment were: Baltimore, Chicago-West Side, Durham, Houston, Memphis, and San Francisco. On-site investigators were identified at each VA site to obtain IRB approvals (i.e. human subjects), mailing addresses and phone numbers from the local database, and establishing on-site contacts for laboratory services for blood collection. A total of 266,099 veterans were identified in a master file.

From the master file of VA users at the six sites, participants were identified for randomization. Veterans were included if they met the following conditions: 1) had no evidence of prostate cancer, 2) had a race code of White, African-American, or unknown, 3) were 45 to 70 years of age, and 4) had no in-patient discharge record of death. Diagnostic and procedure files from the PTF were examined to identify individuals who had a history of prostate cancer or a history of surgical procedures for treating prostate cancer including prostatectomy, TURP, prostate biopsy, or radiation therapy. ICD-9 codes were used to identify prostate cancer diagnoses from PTF diagnostic files. A total of 14,920 (5.6%) veterans had a diagnostic code for prostate cancer. Prostate cancer surgery and other treatment procedures were evaluated in two ways: 1) through examination of in-patient surgical fields in the PTF files according to ICD-9 surgical codes and 2) through examination of out-patient procedure fields in the OPC files via CPT codes. An additional 3,513 (1.3%) individuals had a history of prostate cancer procedures and were removed from the master file. After consideration of the inclusion criteria, the master file consisted of 130,237 individuals; 49.0% of the veteran population extracted at the six VA sites. The racial distribution was 34.5% white, 23.1% African-American, and 42.4% with no known race.

Three exclusion criteria were considered. The first was a history of cancer, except skin cancer. There were 8,456 individuals with a diagnostic record for cancer who were excluded from the master file. The second exclusion criterion was removal of subjects who did not frequently utilize the selected VA medical center. Subjects using satellite clinics or infrequent users of the primary care facility were considered less likely to respond to requests for blood samples. This was applied to four sites - Chicago, Houston, Memphis, and San Francisco - and was defined as less than 90% of all VA visits at the particular site. After applying the first two exclusion criteria, there were 80,720 veterans who remained in the eligible pool of subjects; 35.5% white, 22.3% African-American, and 42.2% with no known race. The third criteria was removal of subjects who were residents of long-term care facilities, homeless shelters, or prisons, and those with incomplete addresses. This exclusion criterion was evaluated after obtaining patient's mailing addresses. Approval to use veteran's addresses to mail surveys was obtained from the VA Freedom of Information Office.

A.2.C Random Selection

Because race was an important independent variable and was not completely recorded in VA administrative data records, we choose the following approach for case selection: 600 cases were randomly selected from each study site; half (300) were African-American, one-fourth

(150) were white, and one-fourth (150) were individuals with no known race. Other work we have conducted on VA Administrative data suggests that most of the "unknowns" are white veterans. From the total pool of 3,600, we excluded 256 subjects with unusable addresses (i.e. long-term care facilities, homeless shelters, prisons, and incomplete addresses). Once these mailing addresses were removed from the pool of subjects, we randomly selected 500 veterans from each site (3,000 overall) to mail surveys (250 African-Americans, 125 whites, and 125 individuals with unknown race).

We created three mailing groups based on different combinations of instrument length and whether they were mailed all surveys at once or staggered over time. We wanted to explore whether veterans willingness to enroll in the study differed by the mailing strategies. Subjects were thus randomized by race to one of three groups: the first group received the long version of the lifestyle survey and the dietary survey, the second group received the short version of the lifestyle survey and the dietary survey, and the third group received the long version of the lifestyle survey only and received the dietary survey after response. The two types of lifestyle surveys are described below.

A.3 Survey Approaches – Baseline Data

We developed a lifestyle survey to collect baseline health, demographic, quality of life, and medical history data. Two versions of the lifestyle survey were crafted to test survey response based on survey length and time to completion. Dietary data was collected using the Harvard Food Frequency Questionnaire (HFFQ), which is a standard, validated instrument to collect dietary and nutrient data that has been used in many epidemiological cohort studies.

A.3.A Lifestyle Survey

Two versions of a lifestyle survey with different lengths were developed to collect baseline information including demographics, medical history, lifestyle behaviors (such as smoking and physical activity), and information on social networks. Response to different survey lengths and different survey approaches was tested to determine the optimum strategy for obtaining response. Questions on both versions were adapted from many validated health and lifestyle instruments and pilot tested in other related studies.¹⁰ The long version contained 38 questions and was seven pages in length. The shorter version was four pages long and contained 18 questions (both surveys are located in Appendix B). Both surveys were designed with Cardiff/Teleform scanning software that allowed us to scan incoming surveys in-house.

A.3.B Dietary Survey

Dietary information was collected using the Harvard Food Frequency Questionnaire (HFFQ). This accompanied a version of the lifestyle survey in the baseline mailing. The HFFQ assesses average intake of specified foods, supplemental vitamins, and beverages and has been used extensively in epidemiological studies assessing nutritional components (Appendix C).

A.3.C Telephone Survey

A follow-up phone survey was developed to ascertain reasons for non-response from veterans who did not return the mailed survey (Appendix D). Those that told us they did not want to participate or returned the survey unanswered were not contacted. We initially tested the instrument on approximately 100 veterans who were part of another cohort development project (the Early Stage Prostate Cancer Cohort – Pilot Project¹⁰) that assessed factors associated with prostate cancer development. Allowing some open-ended questions helped us refine the questions and improve our protocol for implementing the phone survey.

The survey instrument contains questions about physical and cognitive reasons for not wanting to participate, as well as questions about their health care utilization and satisfaction. In the first part of the survey information about the call is recorded, such as time of day and a summary of the results. Upon making contact with the non-responder the interviewer introduces him/herself and asked if the non-responder ever received the mailed survey. Depending upon the response of the participant the interviewer skips to a separate section of the questionnaire. One section was designed for mail non-responders that recalled receiving the mailed survey instrument while the other section contained questions answerable by mail non-responders that had no recollection of the survey. All mail non-responders were asked if they had ever been diagnosed with prostate cancer, which would preclude them from further participation in the study. All mail non-responders were also asked about their use of the VA hospital and if the care they had received was satisfactory. Previous experience and opinions about VA research was accessed as well as basic demographic information including race and education level. For mail non-responders that recalled the mailed survey twelve additional questions were asked that specifically referred to the details of the mailed survey and possible reasons for not responding to the survey. Interviews could be terminated at any time by the interviewee.

The protocol for implementing the phone survey involved the following: At least one attempt was made to contact the participant morning, afternoon, and evening (with adjustments made for different time zones). Occasionally calls were made on Saturday if necessary to reach mail non-responders. Callers were instructed to make a maximum of eight calls to reach African Americans while a maximum of five calls were made to White Americans. Throughout the duration of the study there were six callers. Each caller was trained on how to deliver the survey and how to categorize the response of the interviewee, so that all interviews could be delivered in a consistent manner. The phone calling team, to further eliminate potential interviewer bias, periodically reviewed survey results.

A.4 Survey Administration

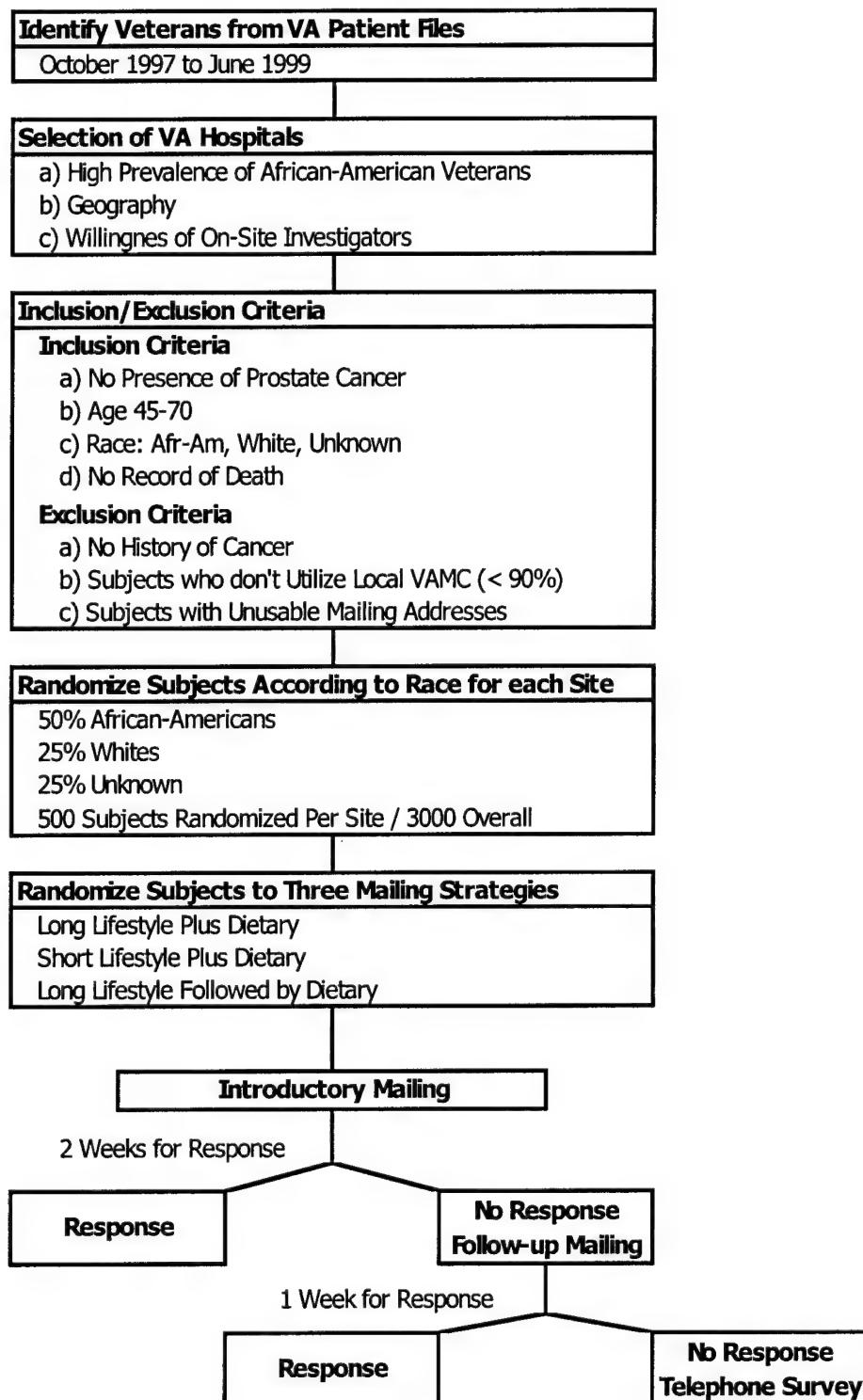
A.4.A Core Survey Sample

Survey mailings were conducted in a staggered fashion once sites obtained IRB approval for human subjects research and laboratories were established to draw blood. A flowchart of the core survey sample procedures is provided in Figure 1. We selected three mailing strategies to determine the optimum method for obtaining response. In the first approach, subjects were sent the long version of the lifestyle survey along with the dietary assessment. In the second approach subjects were sent the short version of the lifestyle survey along with the dietary

assessment. The third approach was a staggered mailing in which only the long version of the lifestyle survey was sent. The dietary assessment was sent upon receipt of the lifestyle survey. The mailing approaches were assigned equally across the three racial groups (White, African-American, and unknown race).

The survey package included an introductory letter describing the study, a sheet outlining survey instructions and requesting blood, a consent form for participating, a version of the lifestyle and the dietary survey depending on the survey group, and a business reply envelope to return the surveys. Introductory letters, instructions, and consent forms were site specific depending on IRB requests from each site. Subjects were asked to complete the surveys and sign and date a consent form to participate in the study. Examples of these documents are provided in Appendix E. Introductory packages were staggered over the first week of mailing. After two weeks a follow-up package was sent. A week after the follow-up package was sent phone calls were made to those that did not return the survey to determine reasons for non-response.

Subjects willing to donate a sample of blood were sent information on having blood drawn at their local VA. The letters included directions to phlebotomy labs, an informed consent form for the blood draw, and a blood tracking form to be completed by the lab. The blood tracking form collected information on the time and day of blood draw and the time since last meal to flag fasting blood samples. Blood collection documents are provided in Appendix F. Participants were asked to sign and date a consent form prior to the blood draw that was witnessed by the laboratory technician. Blood samples were then sent to the MAVERIC Core Blood Lab at the Boston VAMC for storage.

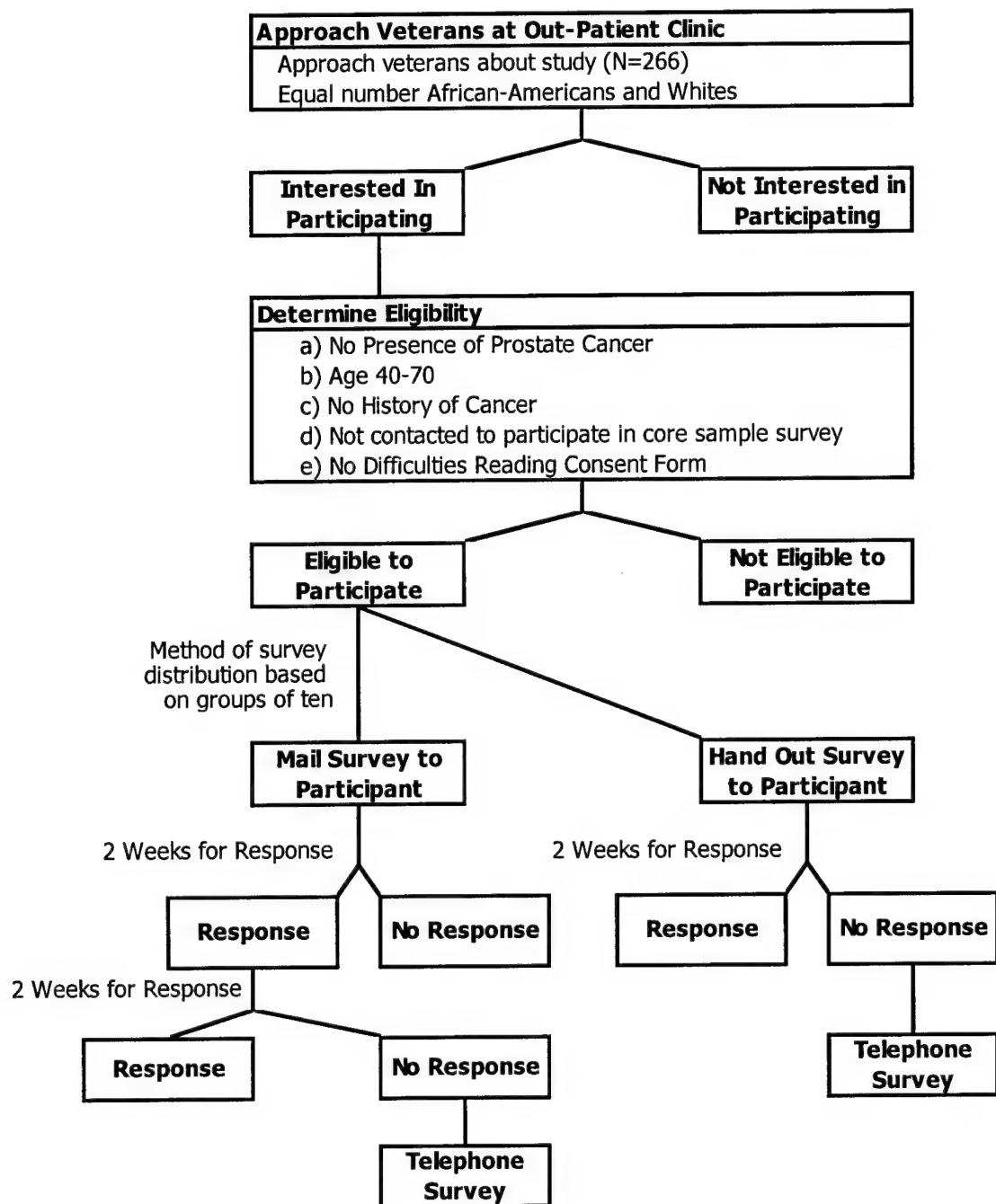
Figure 1: Flow Chart of Core Survey Approach

A.4.B Face to Face Sample

An additional component of this project was the direct recruitment of participants by a trained research assistant at one study site. The Baltimore VA medical center was selected as the site for face-to-face recruitment. A flowchart of the face-to-face sample procedures is provided on the next page in Figure 2. On-site interviewers attempted to approach 500 veterans (equal numbers of African-Americans and Whites) at the ambulatory care clinic and asked them to participate in the project. Interviewers were trained in methods to approach veterans and request participation in the study. Individuals that refused were asked to take part in a non-response interview similar to the telephone survey that followed the core survey mailing. Those that were interested in participating were asked questions about eligibility. The criteria for eligibility were similar to the sample selection criteria outlined in the construction of the core sample (see Sample / Case Selection). Subjects were veterans who did not receive the survey previously by mail. They could not have a diagnosis of prostate cancer or other type of cancer (excluding skin cancer) and had to be 40-70 years of age. If the subject met the eligibility criteria he was consented to participate in the cohort. Subjects who had difficulty reading the consent form, either because of vision or reading comprehension problems, were subsequently not enrolled and were classified as ineligible.

Two survey approaches were assessed with eligible and consented subjects. One group was handed surveys to complete at home along with a return envelope. If the surveys were not returned within four weeks, the participant was contacted by phone and the non-response survey was completed. The other group was mailed surveys once they agreed to participate on-site. A follow-up survey was sent if they did not return the survey within two weeks. The participant was contacted by phone if they did not return the follow-up survey after a week. The survey approach was based on two convenience groups of ten subjects: one receiving the survey to take home and the other receiving the survey in the mail. This same rotating schedule was continued for the rest of the surveys.

Those that agreed to participate were asked to donate a sample of blood at that time. They were directed to the phlebotomy lab with a blood tracking form and a consent form for the blood draw. Participants were asked to sign and date a consent form prior to the blood draw that was witnessed by the laboratory technician. Blood samples were then sent to the MAVERIC Core Blood Lab at the Boston VAMC for storage.

Figure 2: Flow Chart of Face-to-Face Survey Approach

A.5 Analyses of Study Data

A.5.A Core Survey Sample

To assess the feasibility of establishing a veteran cohort of men without prostate cancer, response to the survey was examined overall, by site, and by demographic and utilization characteristics of the participants. Survey response was calculated using both a Microsoft Access tracking database and SAS software.

Veterans who answered questions on either survey were classified as a "Responder." Those who did not respond to surveys, indicated that they did not want to participate in the study, or returned the survey unanswered were classified as "Non-Responders." Subjects who could not be contacted by mail (i.e. surveys were returned to us) were considered "Unable to Contact". Veterans who were deceased or had a diagnosis of prostate cancer were considered "Ineligible."

The response classification was adjusted based on contact through the telephone survey. Since we were interested in survey response that was not initiated by a telephone contact, we excluded surveys that were received after a phone survey call. However, we did allow for cases in which the survey mailing overlapped with the telephone contact. For instance, a participant may have mailed surveys within the time of our telephone call. Therefore, subjects whose surveys were received within seven days of the phone call were classified as responders where as those whose surveys were received outside seven days were classified as non-responders.

Survey response was first evaluated for the four categories mentioned above. Subjects who were ineligible to participate and those that could not be contacted by mail (i.e. those classified as "Ineligible" or "Unable to Contact") were removed from the denominator when calculating response rates.

Patient factors that could influence survey response were evaluated to determine their impact on our survey results. Four types of factors were considered: 1) survey mailing strategies; 2) geographic variation; 3) demographic characteristics; and 4) utilization of VA medical center services. To assess survey mailing strategies, survey response rates were calculated for the three mailing approaches. Geographic variation was evaluated by comparing survey response by site. Demographic factors included race, age, and a means test variable (this variable reflects socio-economic status). These three variables were obtained from VA administrative data files. Race was defined as African-American, White, and subjects with no defined race (Unknown). Age was evaluated as three categories: 45-54, 55-64, and 65-70 (age inclusion was 45-70 years). The means test variable indicates level of eligibility to VA healthcare services defined as: "Category A Service Connected"; "Category A Non-Service Connected"; "Category C"; and "Not Applicable". Veterans that are Category A Service Connected are eligible to use VA sources based on a service connected disability. Category A Non-Service Connected are veterans eligible to receive VA services based on low income status. Category C are veterans who elect to receive VA services and make co-payments for services. Those classified as "Not Applicable" were excluded from analyses of this factor. Utilization of VA services was defined as the frequency of outpatient visits six months prior to survey mailing. Subjects within the lowest quartile were coded as low users; subjects within the two middle quartiles were coded as

moderate users; and subjects within the upper quartile were coded as high users. The association between survey response and patient factors was examined using χ^2 tests.

A.5.B Face-to-Face Sample

The evaluation of response with the face-to-face sample was similar to the core survey approach. Survey response was examined overall, by site, and by demographic and utilization characteristics of the participants. Survey response was calculated using both a Microsoft Access tracking database and SAS software.

Veterans approached for the survey were enrolled if they agreed to participate and met the eligibility criteria. The recruitment material is located in Appendix G. Those who returned the materials and answered questions on either survey were classified as a "Responder". Those who did not respond to our requests, or indicated that they did not want to participate in the study or returned the survey unanswered after the mailing were classified as "Non-Responders". Subjects who could not be reached by mail (i.e. surveys were returned to our office after recruitment because of an unusable address) were considered "Unable to Contact". Response classification was adjusted based on contact through the telephone survey as it was with the core sample data. Subjects whose surveys were received within seven days of the phone call were classified as responders whereas those whose surveys were received outside seven days were classified as non-responders.

Survey response was initially calculated for the four categories mentioned above. Subjects who were ineligible to participate and those that could not be contacted by mail (i.e. those classified as "Ineligible" or "Unable to Contact") were removed from the denominator when calculating response rates.

Patient factors that could influence survey response were evaluated to determine their impact on our survey results in the face-to-face approach. A similar set of factors was assessed in the face-to-face sample including mailing strategy (mailed versus handed to participant), race, age, means test variable, and utilization of outpatient services. Race and age were based on what was reported in the face-to-face interviews. The age criterion was 40-70 years for the face-to-face sample and was evaluated as four categories (40-44, 45-54, 55-64, 65-70). The means test variable was obtained from VA administrative data files. Utilization was defined as frequency of outpatient visits six months prior to date of interview. Subjects within the lowest quartile were coded as low users; subjects within the two middle quartiles were coded as moderate users; and subjects within the upper quartile were coded as high users. The association between survey response and patient factors was examined using χ^2 tests.

A.5.C Analysis of Telephone Survey Data of Non-Responders

All callers were asked to summarize each attempted call into one of eleven categories (see page one of the phone survey Appendix H). The results from the final call were used in the analysis. Three natural groups were formed from the eleven categories in order to better describe the population that was willing to discuss their reasons for not responding to the mailed survey.

- 1) Completed the interview. Responses include: "Successful interview", and "Does not recall/did not receive survey." This includes any non-responder to the mailed survey that completed the phone survey interview.
- 2) Unable to participate in the interview. Responses include: "unwilling to participate", "unable to participate due to health reasons", "has prostate cancer", "already mailed survey", and "Other Reason". This includes any non-responder to the mailed survey that was reached by phone.
- 3) Not able to reach by phone. Responses include: "No answer/ busy", "Left message", "Wrong phone number", and "Phone disconnected". This includes any non-responder to the mailed survey who had a phone number but was unable to be reached in the number of attempted phone calls.

Each of the three groups was characterized by race, site, survey method, age, means test indicator of income, and utilization of VA hospital services (see section A5A for definition of these variables). Interviewees were then further classified into two groups of those that recalled receiving the survey and those that did not recall the survey. A division was necessary due to the interactive nature of the survey, which was tailored to the response of the participant. These groups were again compared on the basis of race, site, survey mailing strategy, age, means test indicator, and utilization of VA services.

Specific reasons for non-response were further analyzed by race and means variables. Education level was also included in this analysis. Participants from "other" racial groups were not considered in this analysis because the design of the study only intended to include white and African American veterans.

Detailed results regarding the specifics of the mailed survey were only available from a subgroup of interviewees that recalled the mailed survey. A factor analysis indicated natural groups of questions from the interview. Three questions were specific to the length of the questionnaire, another set evaluated the ability of the interviewee to comprehend the survey instrument and its instructions, additional questions were asked about concern for confidentiality, and final questions involved the interviewee's health and relationship with the VA hospital. The interviewer was instructed to allow some open-ended discussion to further investigate reasons for non-response. Responses were compared by race and means test indicator.

Data collected from the survey was scanned to an Excel Database and imported to SAS, where results were analyzed. All bi-variable analyses of categorical variables used Chi-square tests for statistically significant findings. In cases of small cell counts Fisher's Exact Test or Monte-Carlo Simulation were applied.

A.5.D Analysis of Baseline Lifestyle and Dietary Survey Data

Univariate descriptive summary statistics of data from the survey at baseline was determined including frequencies and percentiles for categorical variables and means and/or medians for continuous variables. The frequency of missing responses and outlier values to survey questions was assessed. Racial comparisons in question response was determined for certain survey questions.

B RESULTS

B.1 Core Survey Sample

B.1.A Overall Survey Response

Of the 3000 veterans who were mailed surveys, 671 (22.4%) completed surveys and were defined as "Responders". A total of 2064 (68.8%) did not respond to the survey request and 14 (0.5%) were unwilling to participate or returned the surveys unanswered. These subjects were examined together as "Non-Responders" with a total of 2078 (69.3%) veterans. Furthermore, 24 (0.8%) veterans were deceased; 17 (0.7%) veterans were ineligible because they had a prostate cancer diagnosis; and 210 (7.0%) could not be contacted by mail (packages were return to sender).

The response rate excluding those who were deceased, ineligible or unable to contact was 24.4% (671/2749). Response rates in the subsequent analyses of the core sample are based on those subjects that could be contacted and were eligible to participate in the cohort (N=2749). Results are presented on the next page in Table 1.

B.1.B Factors Associated with Survey Response

B.1.B.1 Race

Response to the survey was lower among African-Americans with 19.4% (270/1391) of this group responding to the survey. Response was higher among white veterans with 29.4% (205/698) completing the survey and those with no reported race with 29.7% (196/660) completing the survey. This association was statistically significant at $p < 0.001$.

B.1.B.2 Geographic Variation

Survey response was greater than 20% for each site. The highest response rate was at the Durham VA Medical Center with 31.3% (148/473) of the veterans completing the survey. Response was 25.8% (118/457) at the San Francisco VA, 24.1% (110/456) at the Baltimore VA, 23.3% (107/460) at the Memphis VA, 21.2% (95/448) at the Chicago VA, and 20.4% (93/455) at the Houston VA. This association was statistically significant at $p = 0.002$.

B.1.B.3 Survey Mail Strategies

Three mailing approaches were evaluated which included a long lifestyle and dietary survey, a short lifestyle and dietary survey, and a long lifestyle survey followed by a dietary survey for responders. There was no difference in response rates between the three mailing approaches. Response rates were 22.6% (203/898) for the long lifestyle plus dietary group, 26.1% (242/929) for the short lifestyle plus dietary group, and 24.5% (226/922) for the long lifestyle followed by dietary group ($p = 0.230$).

Table 1: Response to Survey and Characteristics of Response - Core Survey Sample*

		Responders		Non-Responders		p-value
		N	%	N	%	
Overall Response		671	24.4%	2078	75.6%	
Race	African-American	270	19.4%	1121	80.6%	<0.001
	White	205	29.4%	493	70.6%	
	Unknown	196	29.7%	464	70.3%	
VA Medical Center	Baltimore	110	24.1%	346	75.9%	0.002
	Chicago	95	21.2%	353	78.8%	
	Durham	148	31.3%	325	68.7%	
	Houston	93	20.4%	362	79.6%	
	Memphis	107	23.3%	353	76.7%	
	San Francisco	118	25.8%	339	74.2%	
Survey Type	Long Plus Diet	203	22.6%	695	77.4%	0.230
	Short Plus Diet	242	26.1%	687	74.0%	
	Long Followed by Diet	226	24.5%	696	75.5%	
Age	45-54 Years	302	22.3%	1055	77.8%	0.001
	55-64 Years	225	29.2%	545	70.8%	
	65-70 Years	144	23.2%	478	76.9%	
Means Test Indicator †	Cat A NSC	386	22.1%	1363	77.9%	0.001
	Cat A SC/SPEC	218	28.0%	562	72.1%	
	Cat C	57	30.0%	133	70.0%	
Utilization of VA Out-Patient Services §	Low Utilizers	169	20.1%	673	79.9%	0.002
	Moderate Utilizers	324	26.1%	917	73.9%	
	High Utilizers	178	26.7%	488	73.3%	
* N=2749 excludes subjects who were ineligible, either because of a prostate cancer diagnosis or death, and subjects who could not be contacted by mail.						
† Means Test Indicator - Levels of Variable Described in Text						
§ Utilization Defined as Out-Patient Visits 6 Months Prior to Introductory Mailing						

B.1.B.4 Age

Age was evaluated for three groups: 45-54 years, 55-64 years, and 65-70 years. Response was highest among veterans between 55 and 64 years of age with 29.2% (225/770) responding to our request. The response rate was similar between the two other age groupings with 22.3% (302/1357) responding in the 45-54 age group and 23.2% (144/622) responding in the 65-70 age group. This association was statistically significant at $p = 0.001$.

B.1.B.5 Means Test Variable

Response to the survey was highest among Category A Service Connected and Category C veterans but was low among veterans that were Category A Non-Service Connected. The response rate for Category A Non-Service Connected was 22.1% (386/1749). This group made up the majority of the veterans contacted in this study. The response rate was 28.0% (218/780) for Category A Service Connected and 30.0% (57/190) for Category C. This association was statistically significant at $p = 0.001$.

B.1.B.6 Outpatient Utilization

Survey response also differed by the frequency of VA outpatient health services. Utilization was defined as the number of outpatient visits at the VA by each participant six months prior to receiving surveys. The minimum number of visits was zero for the six month period and the maximum was 169 visits, with the median being 3 visits. The three categories defined for this analysis were: low utilizers (no visits within the time period), moderate utilizers (1-6 visits), and high utilizers (7-169 visits). The largest response was observed among veterans who were moderate or high utilizers of VA outpatient services. The high utilizers had a response rate of 26.7% (178/666), followed by moderate utilizers who had a response rate of 26.1% (324/1241). The lowest response was observed among low utilizers who had a response rate of 20.1% (169/842). This association was statistically significant at $p = 0.002$.

B.1.B.7 Means Test Variable Stratified by Age

The means test variable was assessed by age group (see Table 2). The overall effect of this factor on survey response was observed for subjects 55-70 years of age, but not for subjects 45-54 years of age. Among those 55-70 years of age, the response rates were 22.3% (210/942) for Category A Non-Service Connected, 34.2% (116/339) for Category A Service Connected, and 38.4% (38/99) for Category C ($p < 0.001$). For those 45-54 years of age the response rates ranged from 20.9% to 23.1% for the three categories ($p = 0.825$).

B.1.B.8 Means Test Variable Stratified by Utilization

The effect of the means test was also examined by outpatient utilization. The overall result for survey response was observed for low utilizers of VA outpatient services (zero visits six months prior to the mailing), but not for moderate and high utilizers (1-6 visits and 7-169 visits within the same period, respectively). Among low utilizers, the response rates were 15.7% (83/528) for Category A Non-Service Connected, 27.7% (47/123) for Category A Service Connected, and 26.1% (31/119) for Category C ($p < 0.001$). Response rates did not differ for moderate utilizers ($p = 0.146$) and high utilizers ($p = 0.124$). Response rates are presented in Table 2.

Table 2: Effect of Means Test Variable on Survey Response Stratified by Age and Utilization of VA Outpatient Services - Core Survey Sample

		Responders		Non-Responders		p-value	
		N	%	N	%		
Means Stratified by Age							
Age 45-54 (N=1339)							
Means Test Indicator †	Cat A NSC	176	21.8%	631	78.2%	0.825	
	Cat A SC/SPEC	102	23.1%	339	76.9%		
	Cat C	19	20.9%	72	79.1%		
Age 55-70 (N=1380)							
Means Test Indicator †	Cat A NSC	210	22.3%	732	77.7%	< 0.001	
	Cat A SC/SPEC	116	34.2%	223	65.8%		
	Cat C	38	38.4%	61	61.6%		
Means Stratified by Out-Patient Utilization							
Low Utilizers (N=817)							
Means Test Indicator †	Cat A NSC	83	15.7%	445	84.3%	< 0.001	
	Cat A SC/SPEC	47	27.7%	123	72.4%		
	Cat C	31	26.1%	88	74.0%		
Moderate Utilizers (N=1236)							
Means Test Indicator †	Cat A NSC	197	24.4%	610	75.6%	0.146	
	Cat A SC/SPEC	106	28.5%	266	71.5%		
	Cat C	19	33.3%	38	66.7%		
High Utilizers (N=666)							
Means Test Indicator †	Cat A NSC	106	25.6%	308	74.4%	0.124	
	Cat A SC/SPEC	65	27.3%	173	72.7%		
	Cat C	7	50.0%	7	50.0%		

† Means Test Indicator - Levels of Variable Described in Text - Excludes 30 subjects with no eligibility.

B.1.C Response to Request for Blood Sample

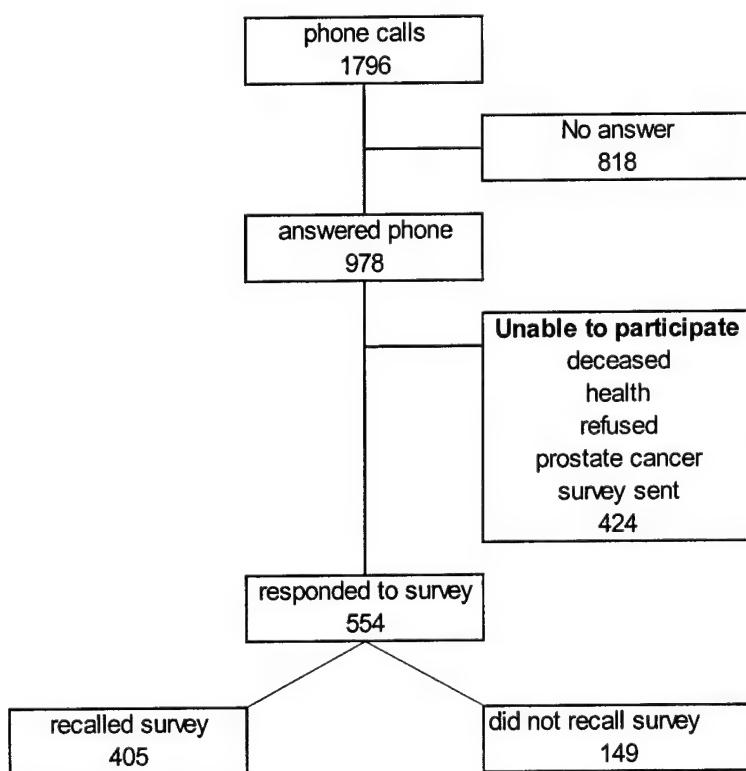
Approval to have blood drawn was approved by IRBs at five of our sites. Blood drawing issues were not resolved with Chicago who wanted more descriptive information about future genetic tests. Excluding Chicago, 70.0% (403/576) of the survey responders agreed to the blood donation request in the survey packet. Those that were interested were sent information about where to donate blood at their local VA site. Of the 403, there were 128 (31.8%) who donated a sample of blood. African-American subjects and subjects with no recorded race had lower responses to blood donation (29.6% and 25.8%, respectively) compared to White subjects (39.4%) ($p = 0.049$). Response also varied geographically with greater response at Houston (48.6%), Memphis (39.4%), and San Francisco (39.3%) compared to Durham (21.1%) and Baltimore (15.3%) ($p < 0.001$).

B.1.D Telephone Survey of Non-Responders

B.1.D.1 Outline of Participation in Phone Survey

Of the 2064 mail non-responders, 1796 had phone numbers listed in the VA databases. Only 978 of the mail non-responders were reached by phone. 424 participants refused or were unable to participate in the survey due to health reasons, leaving 554 completed interviews. The number of questions asked varied depending on whether the participant recalled the mailed survey. See Figure 3 below.

Figure 3: Outline of Participation in Phone Survey



B.1.D.2 Characteristics of Phone Sample

The 1796 mail non-responders for the phone survey were characterized by data made available by VA patient databases (Table 3). These characteristics included race, local VAMC, survey type, age, means test indicator, and utilization of outpatient services. Those that completed the interview were classified as the reference group to be compared with groups that were unable to be reached or unable to participate. Age ($p=0.0001$), VA medical center ($p=0.0029$), utilization ($p<0.0001$), and race ($p<0.0001$) were found to be significantly associated with willingness to complete the phone survey. Racial group participation rates may have been biased by differences in the number of attempted phone calls. Callers were instructed to make a maximum

of eight calls to reach African Americans while a maximum of five calls were made to White Americans. The participant's race was confirmed by the interviewer reducing the number of "unknowns" in the "completed interview" category. The youngest age group of 45-54 year olds was the most difficult to reach with 52.3% unreachable after several phone calls. Utilization positively affected response rate with high VA users having a higher response rate than low VA users. Baltimore had the lowest proportion of completed interviews (24%) compared to Houston, which had the highest proportion of completed interviews (35%). The significant finding for VA medical center may be explained by race mediating the effect measured between response and VA medical center ($p<0.001$) (data not shown).

The phone survey was administered in two parts depending on the mail non-responders recollection of the phone survey. Characteristics of the two categories of interviews are reported in Table 4. Race ($p=0.0007$) and VA Medical Center ($p=0.0161$) were found significantly associated with recollection of the mailed survey. White Americans were the most likely to recall the survey. 83% of White Americans recalled receiving the mailed survey compared to 68% of African Americans. Participants from Chicago (64%) were the least likely to recall the survey while participants from Durham (87%) were most likely to recall the survey. The interrelationships between site, race and means test may explain these regional differences ($p=0.0011$) (data not shown).

Similar questions were asked of both mail non-responders that recalled the mailed survey and mail non-responders that did not recall the mailed survey. Table 5 illustrates the relationship between race and specific questions asked of all mail non-responders who participated in the phone survey. Significant differences in question response occurred in the participant's evaluation of his experience with the VA ($p=0.03$). African Americans (80%) were more likely to give a positive evaluation of their care at the VA than white Americans (70%). The proportion of infrequent users was almost double among white Americans (19%) compared to African Americans (11%).

Characteristics of participants in the phone survey were also stratified by the means variable (Table 6). Quality of VA experience ($p=0.0107$), prior participation in research ($p=0.0013$), and education ($p=0.0108$) were significantly associated with the means test indicator. Overall most participants expressed positive sentiments about the care that they had received from the VA. Category C participants were the least likely to visit the VA (40% infrequent care) compared to Category A service connected injury (10% infrequent care). Category A service connected injury participants had the most experience with surveys and likewise had the most positive experiences with research (20%). Category A service connected and category C participants had relatively similar distributions of education level. However category A non-service connected had a lower distribution of education level with 11% only completing grade school, almost twice that of category A service connected (6.8%) and category C participants (6.1%).

Table 3: Characteristics of Phone Sample by Response Category

	Completed Interview		Unable to Participate			No Answer		
	N	%	N	%	p-value	N	%	p-value
Overall Response	554	30.9%	424	23.6%	<.0001	818	45.6%	<.0001
Race a								
African-American	341	33.6%	234	23.0%		441	43.4%	
White	200	40.5%	111	22.5%		183	37.0%	
Unknown	13	4.6%	79	24.6%		194	67.8%	
VA Medical Center					0.0029			0.1586
Baltimore	76	24.0%	92	29.0%		149	47.0%	
Chicago	106	32.4%	88	26.9%		133	40.7%	
Durham	92	31.0%	73	24.6%		132	44.4%	
Houston	120	35.0%	61	17.8%		162	47.2%	
Memphis	99	32.1%	75	24.4%		134	43.5%	
San Francisco	61	29.9%	35	17.2%		108	52.9%	
Survey Type					0.1147			0.1437
Long followed by Diet	159	27.4%	146	25.2%		275	47.4%	
Long Plus Diet	193	32.6%	127	21.4%		273	46.0%	
Short Plus Diet	202	32.4%	151	24.2%		270	43.3%	
Age					0.0466			0.0001
45-54 Years	241	26.6%	191	21.1%		474	52.3%	
55-64 Years	174	36.9%	105	22.3%		193	40.9%	
65-74 Years	139	33.3%	128	30.6%		151	36.1%	
Means Test Indicator †					0.9631			0.4505
Cat A NSC	365	30.7%	279	23.5%		545	45.8%	
Cat A SC/SPEC	152	32.1%	115	24.3%		206	43.6%	
Cat C	33	27.5%	27	22.5%		60	50.0%	
Utilization of VA Out-Patient Services §					0.5959			<.0001
Low Utilizers	144	25.8%	119	21.3%		296	53.0%	
Moderate Utilizers	260	33.3%	185	23.7%		336	43.0%	
High Utilizers	147	35.6%	105	25.4%		161	39.0%	

* N=1900 only includes participants that were contacted by phone

"Completed interview" is the reference group for all tests.

a Recruitment efforts were not unbiased

† Means Test Indicator - Levels of Variable Described in Text

§ Utilization Defined as Out-Patient Visits 6 Months Prior to Introductory Mailing

Table 4: Characteristics of Responders to the Phone Survey by Recollection of the Mailed Survey

		Recall Survey		Do Not Recall Survey		p-value
		N	%	N	%	
Overall Response		405	73.1%	149	26.9%	
Race	African-American	230	67.5%	111	32.6%	0.0007
	White	165	82.5%	35	17.5%	
	Unknown	10	76.9%	3	23.1%	
VA Medical Center	Baltimore	55	72.4%	21	27.6%	0.0161
	Chicago	68	64.2%	38	35.9%	
	Durham	80	87.0%	12	13.0%	
	Houston	88	74.0%	32	26.7%	
	Memphis	69	69.7%	30	30.3%	
	San Francisco	45	73.8%	16	26.2%	
Survey Type	Long Plus Diet	144	74.6%	49	25.4%	0.2041
	Short Plus Diet	139	68.8%	63	31.2%	
	Long Followed by Diet	122	76.7%	37	23.3%	
Age	45-54 Years	179	74.3%	62	25.7%	0.8508
	55-64 Years	125	71.8%	49	28.2%	
	65-74 Years	101	72.7%	38	27.3%	
Means Test Indicator †	Cat A NSC	256	0.7014	109	29.9%	0.1209
	Cat A SC/SPEC	119	0.7829	33	21.7%	
	Cat C	26	0.7879	7	21.2%	
Utilization of VA Out-Patient Services §	Low Utilizers	105	72.9%	39	27.1%	0.6427
	Moderate Utilizers	195	75.0%	65	25.0%	
	High Utilizers	104	70.8%	43	29.3%	

* N=564 only includes participants that agreed to participate in the phone survey.

† Means Test Indicator - Levels of Variable Described in Text. Incomplete data for this category.

§ Utilization Defined as Out-Patient Visits 6 Months Prior to Introductory Mailing

Table 5: Results from Phone Survey for all who Responded Stratified by Race

	African American		White		p-value
	N	%	N	%	
Overall Response	341	63.0%	200	37.0%	<.0001
Quality of VA Experience					0.03
Infrequent care at VA	32	11.2%	33	19.3%	
Frequent care at VA is poor	25	8.8%	19	11.1%	
Frequent care at VA is good	228	80.0%	119	69.6%	
Research Experience					0.6888
Never participated in VA survey	261	80.6%	157	81.4%	
No opinion about survey experience	16	4.9%	7	3.6%	
Bad experience with past survey	6	1.8%	6	3.1%	
Good experience with past survey	43	13.9%	23	11.9%	
Research Benefits Veterans					0.8818
Disagree	28	9.1%	16	8.7%	
Agree	280	90.9%	168	91.3%	
Prostate Cancer is Important Issue					0.0777
Disagree	1	0.3%	3	1.6%	
Agree	312	94.8%	185	96.4%	
Uncertain	16	4.9%	4	2.1%	
Education Level					0.6333
Grade School	38	11.5%	14	7.1%	
High School	138	41.6%	90	45.5%	
Trade School	15	4.5%	12	6.1%	
2 year College	80	24.1%	42	21.2%	
4 year College	37	11.1%	26	13.1%	
Graduate/ Professional School	16	4.8%	9	4.6%	
Participant Refused to Identify	8	2.4%	5	2.5%	

* N=14 responders characterized as "other" race were excluded.

† Self reported race

§ Inconsistent are due to incomplete response data

Table 6: Results from Phone Survey for all who Responded Stratified by Means Test Variable

	Cat A NSC		Cat A SC/SPEC		Cat C		p-value
	N	%	N	%	N	%	
Overall Response	365	66.4%	152	27.6%	33	6.0%	<.0001
Quality of VA experience							0.0107
Infrequent care at VA	41	13.4%	13	9.9%	10	40.0%	
Frequent care at VA is poor	29	9.5%	13	9.9%	2	8.0%	
Frequent care at VA is good	235	77.1%	106	80.3%	13	52.0%	
Research Experience							0.0013
Never participated in VA survey	295	84.3%	99	68.8%	30	90.9%	
No opinion about survey experience	13	3.7%	9	6.3%	1	3.0%	
Bad experience with past survey	4	1.1%	7	4.9%	1	3.0%	
Good experience with past survey	38	10.9%	29	20.1%	1	3.0%	
Research Benefits Veterans							0.0613
Disagree	31	9.3%	8	6.0%	6	19.4%	
Agree	303	90.7%	126	94.0%	25	80.7%	
Prostate Cancer is Important Issue							0.3634
Disagree	3	0.9%	0	0.0%	1	3.1%	
Agree	336	95.2%	138	95.8%	31	96.9%	
Uncertain	14	4.0%	6	4.2%	0	0.0%	
Education Level							0.0108
Grade School	39	11.0%	10	6.8%	2	6.1%	
High School	165	46.4%	49	33.1%	16	48.5%	
Trade School	23	6.5%	5	3.4%	1	3.0%	
2 year College	74	20.8%	45	30.4%	5	15.2%	
4 year College	37	10.4%	21	14.2%	6	18.2%	
Graduate/ Professional School	12	3.4%	12	8.1%	2	6.1%	
Participant Refused to Identify	6	1.7%	6	4.1%	1	3.0%	

* N=14 responders characterized as "other" race were excluded.

† Self reported race

§ Inconsistent are due to incomplete response data

B.1.D.3 Reasons for Non-response

Additional data was collected regarding specific issues about the mailed survey that might have deterred the participant from responding. These questions apply to mail non-responders that recalled the survey by race (see Table 7). Over 50% of both race groups reported that time was a factor in their decision not to complete the survey. Within the table each set of questions is grouped by topic. There was some variation between the opinion of African-American and Whites about the sensitivity of the questions in the mailed questionnaire. Twenty percent of African Americans compared to eleven percent of white Americans indicated that the mailed questionnaire contained questions too sensitive to answer ($p=0.05$).

Table 7: Reasons for Non-Response for those that Recalled the Survey Stratified by Race

	African American		White		p-value
	N	%	N	%	
Overall Response *†	230	58.2%	165	41.8%	0.0011
Length of Questionnaire §					
Questionnaire look too long	75	40.8%	58	43.0%	0.6935
There were too many questions to answer	70	39.6%	52	39.1%	0.936
Participant did not have time to complete survey	104	57.1%	70	51.1%	0.2829
Difficulty Understanding Survey					
Difficulty understanding survey questions	19	10.5%	8	6.0%	0.1615
Difficulty understanding cover letter or instructions	19	10.2%	9	6.5%	0.3795
Questions were too detailed	34	19.8%	17	13.0%	0.1176
Confidence					
Concerned about confidentiality	57	31.3%	35	25.2%	0.2281
Questions were too sensitive	35	20.1%	16	11.9%	0.0523
Unwilling to participate in any research	57	31.3%	35	25.6%	0.26
Health	33	18.2%	23	16.4%	0.6729
History with VA	38	20.8%	24	17.8%	0.5063

* N=11 responders characterized as "other" race were excluded.

This only includes non-responders that recalled the survey

† N reflects positive response to the questions

§ Response to questions are not mutually exclusive, participants could give multiple reasons for not responding

Sample size varied with each question

% reflects positive response within racial group

Data specific to the questionnaire was also stratified by the means test variable (Table 8). Two questions emerged as significantly different among levels of the indicator: survey length ($p=0.0455$), and confidentiality ($p=0.02$). Category C veterans were most likely to be concerned about the length of the questionnaire (64%) and confidentiality of their response (23%). Comparatively, Category A NSC participants were least likely to be concerned about the length of the questionnaire (37%) and confidentiality of their response (24%).

Table 8: Reasons for Non-Response for those that Recalled the Survey Stratified by Means Test

	Cat A NSC		Cat A SC/SPEC		Cat C		p-value
	N	%	N	%	N	%	
Overall Response *†	256	63.8%	119	29.7%	26	6.5%	<.0001
Length of Questionnaire §							
Questionnaire look too long	74	37.0%	44	43.1%	14	63.6%	0.0455
There were too many questions to answer	72	37.7%	38	38.0%	13	59.1%	0.1431
Participant did not have time to complete survey	109	54.0%	51	51.5%	17	73.9%	0.1441
Difficulty Understanding Survey							
Difficulty understanding survey questions	15	7.6%	10	10.0%	1	4.6%	0.633
Difficulty understanding cover letter or instructions	15	7.4%	11	10.6%	0	0.0%	0.2229
Questions were too detailed	29	15.3%	20	20.8%	3	13.6%	0.4614
Confidence							
Concerned about confidentiality	50	24.9%	41	39.8%	5	22.7%	0.02
Questions were too sensitive	27	14.0%	23	23.5%	3	13.6%	0.1144
Unwilling to participate in any research	50	25.0%	36	35.6%	9	39.1%	0.0899
Health	36	17.8%	20	19.6%	1	4.6%	0.236
History with VA	34	17.1%	26	25.7%	4	17.4%	0.1967

* N=4 Means test "Not Applicable" were excluded from analysis

Only includes non-responders that recalled the survey

† N reflects positive response to the questions

§ Response to questions are not mutually exclusive, participants could give multiple reasons for not responding

Sample size varied with each question

Reported percentages reflect positive response within means category

B.1.D.4 Summary

In summary the phone survey allowed us to identify and characterize the reasons for non-response. Most reasons for lack of survey participation may be generalized across racial differences. Among white Americans this research indicates that infrequent use of the VA was particularly associated with decreased response. There was some indication that African Americans may have found some of the questions too intrusive to respond. The means test indicator was not associated with participation in the phone survey but was associated with reasons for not participating in the mailed survey.

B.2 Face-to-Face Sample

B.2.A Results from the Face-to-Face Approach

A total of 266 veterans were approached at the Baltimore VAMC and asked if they would complete questionnaires as part of our study. There were 141 veterans that were ineligible to take part in the study, 121 veterans that were eligible, and four who previously received the survey as part of the core sample mailing (described in Section B.1 above). Of the 141 ineligible veterans, presence of cancer was the reason for 54 veterans and the age criteria was the reason for 86 veterans. One other subject was ineligible because it was felt that he would be non-

compliant with study procedures. Of the 121 veterans eligible for the study, 109 (90.1%) agreed to participate and were consented, while 12 (9.9%) refused to take part in the study. Willingness to participate was more frequent among Whites than African-Americans. For Whites, 40 (93.0%) were willing to participate while three (7.0%) refused. For African-Americans, 69 (88.5%) were willing to participate while nine (11.5%) refused.

Of the 109 who agreed to participate, 52 were mailed surveys and 57 were given surveys at the interview to mail to us. Three of those unwilling to participate were willing to answer questions regarding reasons for non-participation similar to the telephone survey.

B.2.B Overall Survey Response

Of the 109 veterans that were willing to participate, one veteran could not be contacted at the given address. A total of 46 veterans returned completed surveys and were classified as "Responders". Sixty-two (62) veterans did not mail back their surveys and were classified as "Non-Responders". "Non-Responders" were contacted by phone to determine reasons for non-participation.

The response rate excluding the one subject who could not be contacted by mail is 42.6% (46/108). Response rates in the face-to-face sample analyses below are based on this cohort of 108 veterans. Results are presented in Table 9.

B.2.C Factors Associated with Survey Response

B.2.C.1 Race

More African-Americans were approached to participate in the study and were willing to complete surveys. However, the response among African-Americans was lower than Whites. The African-American response rate was 32.4% (22/68) while the response rate among Whites was 60.0% (24/40). The difference in response by race was statistically significant ($p=0.005$).

B.2.C.2 Survey Mail Strategies

Response rates did not vary by survey strategy. Veterans who were handed a survey on site had a response rate of 38.6% (22/57), while veterans who were mailed the survey had a response rate of 47.1% (24/51). The p -value was 0.375.

B.2.C.3 Age

Survey response did not differ by age grouping. The majority of participants were between the ages of 45 and 64 years. Response was 39.2% (20/51) for those 45-54 years and 41.9% (13/31) for those 55-64. Including responses from those less than 45 and greater than 65, the effect of response on age was not statistically significant ($p=0.286$).

B.2.C.4 Means Test Variable

Survey response did not significantly vary by the means test response variable. A greater response was observed among veterans in classified as Category A Service Connected with a

response rate of 48.4% (15/31). The response rate was 40.9% (27/66) for Category A Non-Service Connected and 36.4% (4/11) for Category C. The effect of response by means test variable was not statistically significant ($p=0.713$).

Table 9: Response to Survey and Characteristics of Response – Face-to-Face Survey Sample*

		Responders		Non-Responders		p-value
		N	%	N	%	
Overall Response		46	42.6%	62	57.4%	
Race	African-American	22	32.4%	46	67.7%	0.005
	White	24	60.0%	16	40.0%	
Survey Type	Handing Survey to Veteran	22	38.6%	35	61.4%	0.375
	Mailing Survey to Veteran	24	47.1%	27	52.9%	
Age	40-44 Years	2	25.0%	6	75.0%	0.311
	45-54 Years	20	39.2%	31	60.8%	
	55-64 Years	13	41.9%	18	58.1%	
	65-70 Years	11	61.1%	7	38.9%	
Means Test Indicator †	Cat A NSC	27	40.9%	39	59.1%	0.713
	Cat A SC/SPEC	15	48.4%	16	51.6%	
	Cat C	4	36.4%	7	63.6%	
Utilization of VA Out-Patient Services §	Low Utilizers	13	46.4%	15	53.6%	0.376
	Moderate Utilizers	25	46.3%	29	53.7%	
	High Utilizers	8	30.8%	18	69.2%	

* N=108 excludes subjects who were ineligible because of a prostate cancer diagnosis, and subjects who could not be contacted by mail.

† Means Test Indicator - Levels of Variable Described in Text

§ Utilization Defined as Out-Patient Visits 6 Months Prior to Introductory Mailing

B.2.C.5 Outpatient Utilization

Survey response did not differ by the frequency of VA outpatient health services. Utilization was defined as the number of outpatient visits at the VA by each participant six months prior to recruitment. The minimum number of visits was zero for the six month period and the maximum was 38 with the median being 6 visits. The three categories defined for this analysis were: low utilizers (0-2 visits), moderate utilizers (3-12 visits), and high utilizers (13-38 visits). Low utilizers had a response of 46.4% (13/28), moderate utilizers had a response of 46.3% (25/54), and high utilizers had a response of 30.8% (8/26). The difference in response by outpatient utilization was not statistically significant ($p=0.376$).

B.2.D Response to Request for Blood Sample

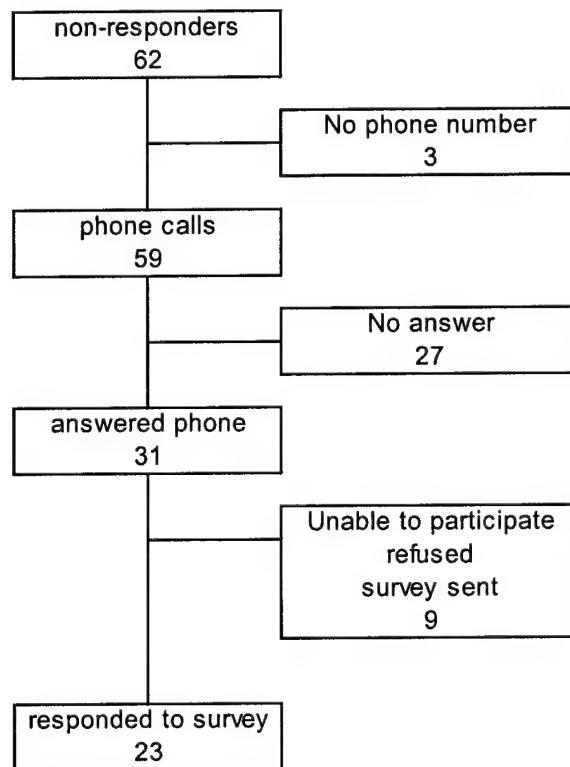
Of the 109 eligible veterans who consented to participate in the study, 35 agreed to donate a sample of blood. Twenty-one (21) of those subjects responded to the survey; nine were African-Americans and 12 were White.

B.2.E Telephone Survey of Non-Responders

B.2.E.1 Outline of Participation in Phone Survey

Out of the 62 non-responders, three did not report a phone number on the face-to-face survey. The remaining 59 were contacted by phone. 27 of these non-responders were unable to be reached after multiple calls. 23 non-responders agreed to discuss their reasons for non-response (See Figure 4).

Figure 4: Outline of Participation in Face-to-Face Phone Survey



B.2.E.2 Characteristics of Face to Face Phone Sample

Characteristics of the face-to-face phone survey sample were extracted from the face-to-face enrollment form and supplemented with information from the VA patient databases. Similar to the core phone survey sample, race, survey strategy, age, means test indicator, and utilization of outpatient services, were used to describe the non-responding population.

Due to small cell sizes, none of the characteristics were found to be significantly associated with response categories. Similar trends prevailed in both the core survey sample and the face-to-face phone survey sample. Although strongly recruited, African Americans were less likely to

complete the phone survey (37.8%). The majority of African-Americans non-responders were unable to be reached by phone (50% no answer). Participants aged 45-54 years old were the most difficult to reach (60 % no answer) over the phone, along with Category C participants (71.4% no answer) and low utilizers of outpatient services (60%). The handout method (45%) slightly increased willingness to participate in the phone survey over the Mailed method (32.1%). (Table 10)

Additional characteristics collected during the phone interview were stratified by race and means variables in tables 11 and 12. Statistical results were not reported because sample sizes were too small to have enough power to detect a significant difference with in the groups. The distribution of education among non-responders in the face-to-face sample was similar to non-responders in the core survey sample and the face-to-face sample. Most participants were at a high school education level (40%). Face-to-face non-responders reported being more satisfied with the care that they receive from the VA (at least 85%) than non-responders in the core survey sample.

Table 10: Characteristics of Face-to-Face Phone Sample by Response Category

	Completed Interview		Unable to Participate			No Answer		
	N	%	N	%	p-value	N	%	p-value
Overall Response	23	39.0%	9	15.3%		27	45.8%	
Race ^a					0.4072			0.4072
African-American	17	37.8%	5	11.4%		22	50.0%	
White	6	40.0%	4	26.7%		5	33.3%	
Survey Type					0.4269			0.4121
Hand-out	15	45.5%	4	12.1%		14	42.4%	
Mailed	8	30.8%	5	19.2%		14	50.0%	
Age ^b					0.8976			0.0889
40-44 Years	2	40.0%	1	20.0%		2	40.0%	
45-54 Years	8	26.7%	4	13.3%		18	60.0%	
55-64 Years	8	47.1%	3	17.7%		6	35.3%	
65-70 Years	5	71.4%	1	14.3%		1	14.3%	
Means Test Indicator †					0.838			0.3349
Cat A NSC	15	40.5%	5	13.5%		17	46.0%	
Cat A SC/SPEC	7	46.7%	3	20.0%		5	33.3%	
Cat C	1	14.3%	1	14.3%		5	71.4%	
Utilization of VA Out-Patient Services §					0.7851			0.1919
Low Utilizers	4	26.7%	2	13.3%		9	60.0%	
Moderate Utilizers	11	39.3%	3	10.7%		15	50.0%	
High Utilizers	8	50.0%	4	25.0%		4	25.0%	

* N=61 only includes participants that were contacted by phone

"Completed interview" is the reference group for all tests.

a Observed race, note that recruitment efforts were not unbiased

b Self reported age

† Means Test Indicator - Levels of Variable Described in Text

§ Utilization Defined as Out-Patient Visits 6 Months Prior to Introductory Mailing

**Table 11: Results from Face-to-Face Phone Survey for All who Responded
Stratified by Race**

	African American		White	
	N	%	N	%
Overall Response	17	73.9%	6	26.1%
Quality of VA Experience				
Infrequent care at VA	0	0.0%	0	0.0%
Frequent care at VA is poor	2	11.8%	0	0.0%
Frequent care at VA is good	15	88.2%	6	100.0%
Research Experience				
Never participated in VA survey	13	81.3%	3	60.0%
No opinion about survey experience	2	12.5%	1	20.0%
Bad experience with past survey	0	0.0%	0	0.0%
Good experience with past survey	1	6.3%	1	20.0%
Research Benefits Veterans				
Disagree	1	6.3%	0	0.0%
Agree	15	93.8%	6	100.0%
Prostate Cancer is Important Issue				
Disagree	0	0.0%	0	0.0%
Agree	17	100.0%	6	100.0%
Uncertain	0	0.0%	0	0.0%
Education Level				
Grade School	1	5.9%	0	0.0%
High School	8	47.1%	2	40.0%
Trade School	1	5.9%	1	20.0%
2 year College	4	23.5%	1	20.0%
4 year College	1	5.9%	1	20.0%
Graduate/ Professional School	1	5.9%	0	0.0%
Participant Refused to Identify	1	5.9%	0	0.0%

[†] observed race

[§] Inconsistencies are due to incomplete response data

**Table 12: Results from Face to Face Phone Survey for All who Responded
Stratified by Means Test**

	Cat A NSC		Cat A SC/SPEC		Cat C	
	N	%	N	%	N	%
Overall Response	15	65.2%	7	30.4%	1	4.4%
Quality of VA experience						
Infrequent care at VA	0	0.0%	0	0.0%	0	0.0%
Frequent care at VA is poor	2	13.3%	0	0.0%	0	0.0%
Frequent care at VA is good	13	86.7%	7	100.0%	1	100.0%
Research Experience						
Never participated in VA survey	11	73.3%	4	80.0%	1	100.0%
No opinion about survey experience	2	13.3%	1	20.0%	0	0.0%
Bad experience with past survey	0	0.0%	0	0.0%	0	0.0%
Good experience with past survey	2	13.3%	0	0.0%	0	0.0%
Research Benefits Veterans						
Disagree	1	6.7%	0	0.0%	0	0.0%
Agree	14	93.3%	6	100.0%	1	100.0%
Prostate Cancer is Important Issue						
Disagree	0	0.0%	0	0.0%	0	0.0%
Agree	15	100.0%	7	100.0%	1	100.0%
Uncertain	0	0.0%	0	0.0%	0	0.0%
Education Level						
Grade School	1	6.7%	0	0.0%	0	0.0%
High School	6	40.0%	4	66.7%	0	0.0%
Trade School	2	13.3%	0	0.0%	0	0.0%
2 year College	3	20.0%	1	16.7%	1	100.0%
4 year College	1	6.7%	1	16.7%	0	0.0%
Graduate/ Professional School	1	6.7%	0	0.0%	0	0.0%
Participant Refused to Identify	1	6.7%	0	0.0%	0	0.0%

[†] Observed race

[§] Inconsistencies are due to incomplete response data

B.2.E.3 Reasons for Non-response

Reasons for non-response were stratified by race and means test variables in Tables 13 and 14. One hundred percent agreed that prostate cancer was an important health care issue. The majority of the participants had no prior experience with research (over 60%). The length of the questionnaire (over 40%) and the time needed to complete the questionnaires (over 30%) were most often offered as explanations for lack of participation. Few confessed any difficulties interpreting the survey materials or concern for confidentiality (25% or less). Cell sizes were too small to be conclusive.

Table 13: Reasons for Non-Response Stratified by Race

	African American		White	
	N	%	N	%
Overall Response ^{††}	17	73.9%	6	26.1%
Length of Questionnaire [§]				
Questionnaire look too long	3	42.9%	2	50.0%
There were too many questions to answer	2	33.3%	2	66.7%
Participant did not have time to complete survey	4	33.3%	2	66.7%
Difficulty Understanding Survey				
Difficulty understanding survey questions	0	0.0%	0	0.0%
Difficulty understanding cover letter or instructions	1	20.0%	2	66.7%
Questions were too detailed				
Confidence				
Concerned about Confidentiality	2	25.0%	0	0.0%
Questions were too sensitive	1	16.7%	0	0.0%
Unwilling to participate in any research	1	14.3%	0	0.0%
Health	0	0.0%	0	0.0%
History with VA	3	50.0%	2	100.0%

This only includes non-responders that completed the phone survey

† N reflects positive response to the questions

§ Response to questions are not mutually exclusive, participants could give multiple reasons for not responding

Sample size varied with each question

% reflects positive response within racial group

Table 14: Reasons for Non-Response Stratified by Means Test

	Cat A NSC		Cat A SC/SPEC		Cat C	
	N	%	N	%	N	%
Overall Response ^{*†}	15	65.2%	7	30.4%	1	4.4%
Length of Questionnaire [§]						
Questionnaire look too long	2	33.3%	2	50.0%	1	100.0%
There were too many questions to answer	2	33.3%	1	50.0%	1	100.0%
Participant did not have time to complete survey	4	44.4%	1	20.0%	1	100.0%
Difficulty Understanding Survey						
Difficulty understanding survey questions	0	0.0%	0	0.0%	0	0.0%
Difficulty understanding cover letter or instructions	0	0.0%	0	0.0%	0	0.0%
Questions were too detailed	1	20.0%	1	50.0%	1	100.0%
Confidence						
Concerned about Confidentiality	1	12.5%	1	50.0%	0	0.0%
Questions were too sensitive	0	0.0%	1	50.0%	0	0.0%
Unwilling to participate in any research	1	16.7%	0	0.0%	0	0.0%
Health	0	0.0%	0	0.0%	0	0.0%
History with VA	3	60.0%	1	50.0%	1	100.0%

Only includes non-responders that completed the survey

* N reflects positive response to the questions

§ Response to questions are not mutually exclusive, participants could give multiple reasons for not responding

Sample size varied with each question

Reported percentages reflect positive response within means category

B.3 Baseline Data

The primary objectives of this pilot study were to determine the feasibility of establishing a cohort of veterans and to determine factors influencing willingness to participate. Those who responded completed the lifestyle and dietary baseline surveys. An analysis of baseline survey data has not been done at this time but it is hoped that many of the patients who participated in this pilot study will enroll in other long-term observation studies of prostate cancer within the VA healthcare system. Baseline data collected in this study may be carried forward to be included in other studies if patients agree to such use of the data and the data is used under an approved study protocol.

KEY RESEARCH ACCOMPLISHMENTS

- Recruitment of on-site investigators at six VA Medical Centers (Baltimore, Chicago-West Side, Durham, Houston, Memphis, and San Francisco)
- Generated a master file of veterans without prostate cancer at the six VAMCs stratified by race.
- Randomly selected 3,600 veterans from the master file to obtain addresses and contact information.
- Developed and pre-pilot tested a lifestyle survey that was sent in conjunction with a dietary assessment instrument (HFFQ) to obtain information on risk factors for prostate cancer incidence.
- Developed and pre-pilot tested a follow-up phone survey that was used to determine reasons for non-response for veterans that did not respond to our mail request.
- Developed and implemented strategies for on-site recruitment of veterans at Baltimore VAMC
- Analyses of study data including factors influencing survey response and ascertainment of reasons for non-response to survey request.

REPORTABLE OUTCOMES

OTHER RELATED STUDIES

Title: Selenium and Vitamin E Cancer Prevention Trial (SELECT)

Description: SELECT is a randomized, double-blind, controlled clinical trial comparing the effects of two supplements, Selenium and Vitamin E, in the prevention or reduction of the occurrence of prostate cancer. Participants are men greater than 55 years of age (greater than 50 for African-American men) who have never been diagnosed with prostate cancer. Eligible participants are randomized to one of four possible study arms: selenium and vitamin E together, selenium only, vitamin E only, or placebo. Participants will be followed every 6 months for 7 to 12 years depending on the year of enrollment.

During the planning of SELECT investigators recognized the challenges recruiting sufficient representation of African Americans into the study. They also realized the pool of potential minorities that could be identified and recruited in the VA healthcare system. This study teamed up with the VA and now includes approximately 40 VA Medical Centers. The co-investigator for our pilot study is now the PI for the VA component of SELECT. Many of the lessons learned in our pilot study contributed to VA involvement in the planning and now execution of this study.

TITLE: Aging Cohort To Improve VEterans Health (ACTIVE HEALTH)

Description: This is a complimentary observational cohort study to the SELECT clinical trial. Men who are contacted about SELECT, may be unwilling to participate in a randomized trial or may be ineligible to participate. The Active Health study is another option. These subjects will be asked to participate in a long-term observational health cohort to assess the incidence and progression of diseases such as heart disease, cancer, diabetes, and kidney disease. Participants are men, 50 years of age or older, with an expected life expectancy of more than five years, that are willing to participate and sign an informed consent form. The primary instrument for baseline data collection will be the SELECT baseline questionnaires. Participants will also be asked to provide a sample of blood for biochemical and genetic analyses, although this is not a requirement for participation. Subjects will be seen on a biannual basis with follow-up telephone interview during the intervening years. During follow-up visits, participants will be asked whether they experienced any medical events since the last study visit, with information on specific diagnoses.

The final step towards completion of our pilot study will be to extend to study participants an invitation to participate in SELECT or Active Health. A letter will be mailed to survey responders indicating study closure and offering the opportunity to participate in these research projects. A postcard accompanying the letter will give participants the opportunity to express their interest. The names of subjects that return postcards will be forwarded to on-site coordinators who will contact willing participants and proceed to enroll them into one of the two research studies.

CONCLUSIONS

The purpose of this study was to evaluate the feasibility of establishing a large cohort of African American males and an equal number of white males for the study of risk factors associated with the incidence of prostate cancer. Current large observational cohort studies typically have had limited success recruiting African Americans and generally have poor representation of minority populations. Lingering mistrust of the American health care system, and research studies in particular, may still be the primary reason for poor participation rates in existing studies. The Department of Veterans Affairs (VA) health care system was thought to provide an ideal setting to establish an observational cohort of African Americans because it serves a large minority population and has an extensive history of successfully conducting research studies with the cooperation of the community of veterans who obtain care in the VA (i.e., VA users).

There were several conclusions from this study: 1) the VA has unparalleled national electronic databases with extensive demographic and clinical information on its user base; information ideal for identification, recruitment, and follow-up of minority populations in observational studies, 2) the response rates to mailed survey approach was lowest among African Americans although rates were low in both African American and white VA users, 3) face-to-face recruitment of VA users was more successful than the survey mailing methods, and 4) reasons for unwillingness to participate in our study were similar for African American and white VA users although African Americans were a little more concerned than whites about confidentiality and sensitivity of questions.

Using VA Data Systems for Observational Studies

The VA electronic databases provide a unique opportunity to identify eligible candidates for the study of factors that may be associated with incidence (as well as progression) of prostate cancer. National administrative data files contain considerable information on all inpatient and outpatient health care encounters in the VA system for all VA users, including the richness of ICD-9-CM and CPT4 diagnostic and treatment coding. These data files share the same unique patient identifier (i.e., scrambled social security number) providing the capacity to link all patient records for cross-sectional and longitudinal analyses. In addition to this process of care data, the VA also maintains a death database (i.e., BIRLS) that has high accuracy in recording all cause mortality.

VA databases provide the opportunity for research investigators to conduct the following activities towards establishing an observational cohort: 1) identify eligible pools of African American and white patients for study due to the availability of race coding for most records in administrative data files, 2) obtain patient mailing addresses for almost all VA users from a national VA data file, 3) compare characteristics of responders and non-responders using demographic characteristics available for the overall VA user population, 4) efficiently obtain information on patient's use of medical services for many years after study initiation, 5) link these data with non-VA data sources (such as Medicare data), and 6) track patient outcomes such as hospitalizations and mortality.

Given these VA data assets we were able to identify a pool of African American and white veteran patients without medical evidence of prostate cancer who were VA users in six VA

Medical Centers throughout the country. Using diagnostic and procedure coding we applied a number of important inclusion and exclusion criteria that helped us efficiently identify qualified subjects for this study and focus our recruitment efforts. For the purposes of this feasibility study we were able to randomly select study subjects among the eligible pool of VA users without prostate cancer and to stratify selection by race.

Response Rates to Mail Survey Among African Americans and White VA-Users

The response rate for both African Americans and white patients was lower than hypothesized (overall response rate was 24%). The response rate for African Americans (19%) was lower than whites (29%). Response rates were lowest for VA users with a non-service connected VA eligibility category, younger VA users, and infrequent VA users. There was some geographic variability in response with lowest response rates at the Houston VA. Response rates were also lowest for patients who received the longer compared to shorter version of the mail survey instrument. Although the response rate for African Americans was lower than whites, the absolute rate for African Americans would still be an improvement over most existing large observational studies. For example, the Physicians Health Study is composed of only 7% minorities while the Nurses Health Study have approximately 2% African-Americans.

Face-to-Face Versus Mail Recruitment Methods

A much higher proportion of patients who were in the face-to-face arm of the study consented to participate in the study compared to those who participated in the mail method. In an outpatient setting at one VA Medical Center a trained research assistant approached 266 VA users who were then invited to participate in the study. Almost all VA users approached were willing to participate in the study. But after responding to some initial screening questions more than half were ineligible due to presence of cancer, above age criteria, or previously received mail survey. Of the remaining 121 eligible patients, 90% consented to enroll. The consent rate was 88% for African Americans and 93% for whites. Although there was one ineligible patient for every eligible patient approached by the research assistant, these consent rates exceeded expectations.

We also calculated the percentage among consented patients that returned a completed mail survey (overall return rate of 43%). Although not statistically significant, the patients who were given a copy of the survey at initial contact had lower response rates (39%) compared to those that were mailed the survey in the following week (47%). Overall whites were much more likely to return the surveys compared to African Americans (60% versus 32%, respectively).

Reasons for Unwillingness to Participate in this Study

The follow-up phone calls to patients that did not return their mail surveys provided a glimpse of the reasons for non-response and suggest some differences between African American and white men. Small sample size limits our power to derive any statistical conclusions based on these data so we can only cautiously suggest possible differences between the two ethnic groups. Of those who recalled seeing the survey in the mail, we asked questions about survey length, interpretation of instrument, and issues of confidentiality. Approximately 40% of both African American and white men indicated that the survey was too long and had too many questions. A greater percentage of white versus African American men indicated that they did not have time

to complete the survey. African Americans were more likely to have difficulties understanding the survey questions or thought questions were too detailed. African Americans also were a little more likely than white men to have issues with confidentiality or think that the questions were too sensitive.

It was surprising that given all the research studies conducted in the VA that approximately 80% of non-responders indicated that they have never participated in any VA research although they also indicated that they receive frequent care from the VA.

Also almost all agreed that VA research does benefit veterans and that, prostate research in particular, was important. For this latter finding there were no substantial difference between African American and white men.

Lessons Learned from Pilot Study

This was a complex pilot test examining different approaches to establishing an observational cohort among African American users of the VA system and understanding the reasons for non-response. Because the design included implementing all the mechanisms for recruiting subjects and collecting baseline data much was learned about administering and managing the different survey methods explored in this study. Albeit anecdotal, some of these insights may be useful to investigators considering or presently conducting observational studies in the VA.

- An electronic tracking system such as Microsoft Access is crucial to survey administration. The Access database was used in this pilot to track every survey mailed out and received by our project office and to track all follow-up phone calls to non-responders.
- All survey instruments were scanned in-house by Cardiff/Teleform scanning except for the dietary instrument with its own bar coded identification that was scanned by the Harvard NCS system at the Channing Laboratory. For even a pilot project of this small size, there still was a considerable manual effort checking and cleaning returned surveys.
- Phone calls were more successful when made during early evening hours.
- Although not directly addressed in this pilot, we think that literacy level of potential subjects has a profound impact on both response rates and the completeness and accuracy of data obtained from mailed surveys.
- We obtained IRB approval at all six participating institutions. Because each IRB had their own unique interpretation of informed consent principles we were required to create separate consent forms for each institution. This process, even working with a local co-investigator, took an enormous amount of time and delayed our schedule of survey mailings. Multi-institutional studies will be challenged by these administrative inconsistencies. We did not collect blood at one facility due to the difficulties in meeting IRB requirements for consenting patients with future genetic testing.

Since the mechanism for contacting patients was through mail survey, special arrangements had to be made for patients to give blood at the laboratories at each VA Medical Center. These

arrangements were different at each facility given varied laboratory practice patterns. Other challenges were created because veterans live varied distances away from their primary point of care (either a Medical Center or Community Based Outpatient Clinic).

Future Research

We did not initiate an application for DoD Phase II funding to expand our pilot cohort because of initiation of two other large VA studies where MAVERIC (Massachusetts Veterans Epidemiologic Research and Information Center) is playing a lead role. While the pilot study was in progress both the PI and Co-PI we're also involved in the planning of two prostate related studies. SELECT (Selenium and Vitamin E Cancer Prevention Trial) is a randomized, double-blind, controlled clinical trial comparing the effects of two supplements, Selenium and Vitamin E, in the prevention or reduction of the occurrence of prostate cancer. SELECT investigators, recognizing the value of VA data and capacity to recruit minorities, teamed up with the VA to include approximately 40 VA Medical Centers into SELECT. ACTIVE HEALTH (Aging Cohort To Improve VEterans Health) is a complimentary observational cohort study to the SELECT clinical trial. Subjects in ACTIVE HEALTH will be asked to participate in a long-term observational health cohort to assess the incidence and progression of diseases such as heart disease, cancer (e.g., prostate), diabetes, and kidney disease. The co-investigator for our pilot study is now the PI for both the VA component of SELECT and ACTIVE HEALTH. Many of the lessons learned in our pilot study contributed to VA involvement in the planning, design, and now execution of these studies.

Summary

In this pilot study we attempted to evaluate different approaches to identifying and recruiting both African American and white veterans. Although our response rates to mail surveys were lower than response rates for the face-to-face recruitment, the mailing approach may still be the most efficient method of recruiting African Americans. A face-to-face method that includes patient interviews (our surveys were mailed) can have four times the study cost compared to a mailed survey method.¹¹ Thus, mailed surveys may be the most efficient approach to recruiting large numbers of African Americans. Compared to the total number of African Americans that could be recruited into an observational study from the general population, the absolute number of African American veterans that could be recruited may still be significantly higher since the VA has a large pool of African American veterans identifiable through VA national administrative databases.

Multiple reasons why African Americans are less willing to participate in research studies than whites are identified in the literature.¹² Lack of trust based on the belief that the motivations of researchers are not in the best interests of participants is frequently cited as the primary barrier to participation. Other barriers include time commitments, family obligations, and past experiences with health care and research studies.¹³ Investigator from one study, in a research design similar to our pilot study, identified factors that influence African American willingness to participate in medical research studies.^{14,15} In this study subjects were initially contacted by mail and then by telephone to assess reasons for non-participation. Some of the reasons expressed by non-responders were that they: did not want to be part of an experiment, feared not receiving the

same treatment, lacked trust in medical researchers, and lacked time to participate. These findings are consistent with trends identified in our pilot study.

We make the following recommendations regarding ways to improve recruitment. Approximately 40% of both African Americans and whites thought the survey was too long or had too many questions, so clearly shortening the amount of time (i.e., response burden) required to complete a survey is important. To better introduce the survey packet to subjects we suggest mailing a pre-notification card. Since approximately 30% of non-responders overall expressed some concern about confidentiality we suggest that the cover letter and introductory materials focus greater attention on how patient confidentiality will be protected.

Additionally, recruitment may be improved by targeting subgroups from the VA administrative data files. Veterans who were frequent users of VA care had higher response rates in our pilot study. Veterans who were eligible for VA care based on a service-connected disability were also more responsive. In addition, veterans between the ages of 55-64 were more responsive than younger and older veterans.

There are many advantages to using the VA healthcare system to establish a large observational cohort for study of disease incidence, prevalence, progression, and/or outcomes in populations well represented by diverse ethnic groups. The recent funding and initiation of SELECT and ACTIVE HEALTH reflect this sentiment. Results from this pilot study have helped researchers at MAVERIC focus its prostate cancer research mission and take full advantage of opportunities in the VA to use observational studies that are well represented by African American men.

DAMD17-98-1-8646

Final Report

March 21, 2002

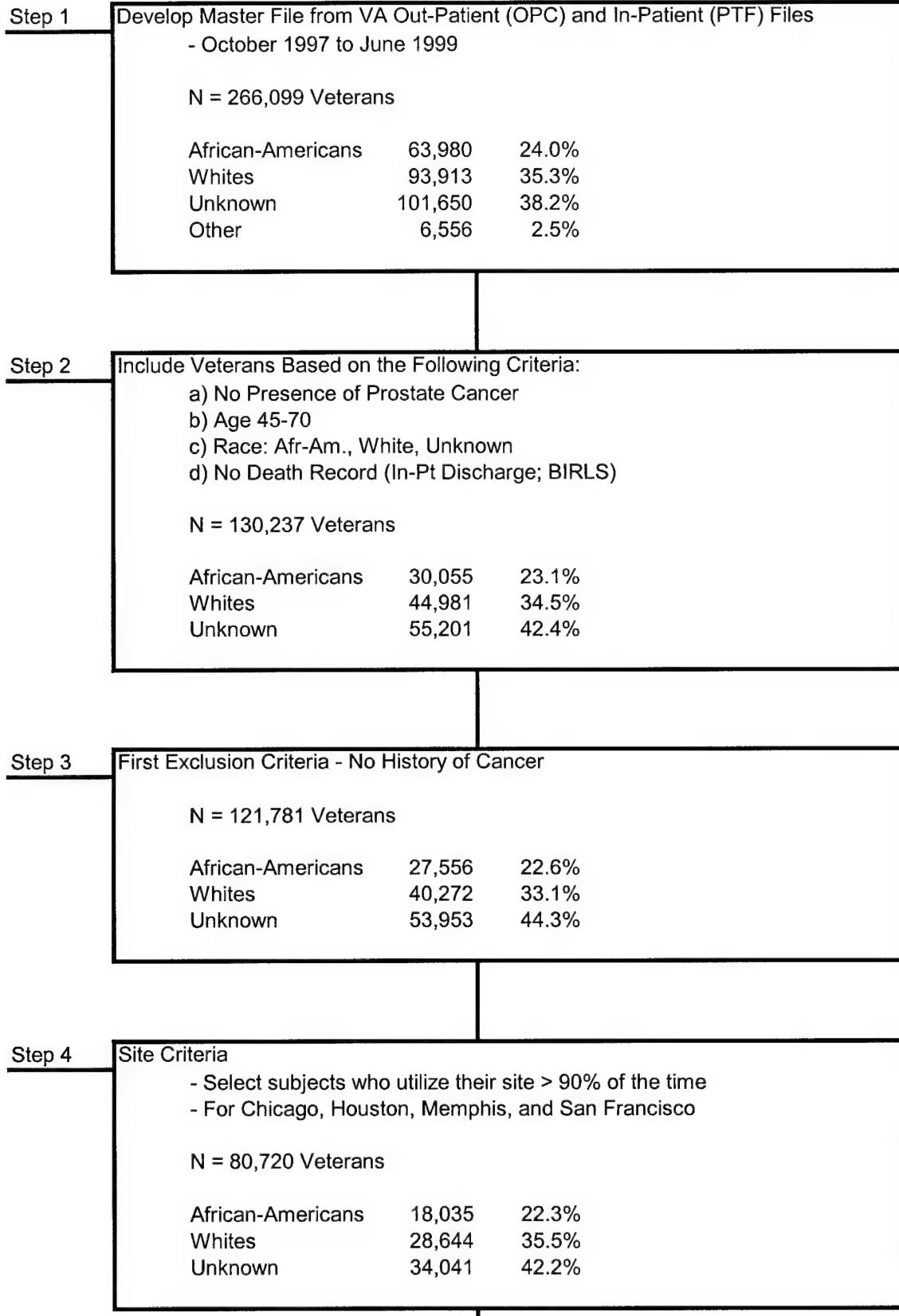
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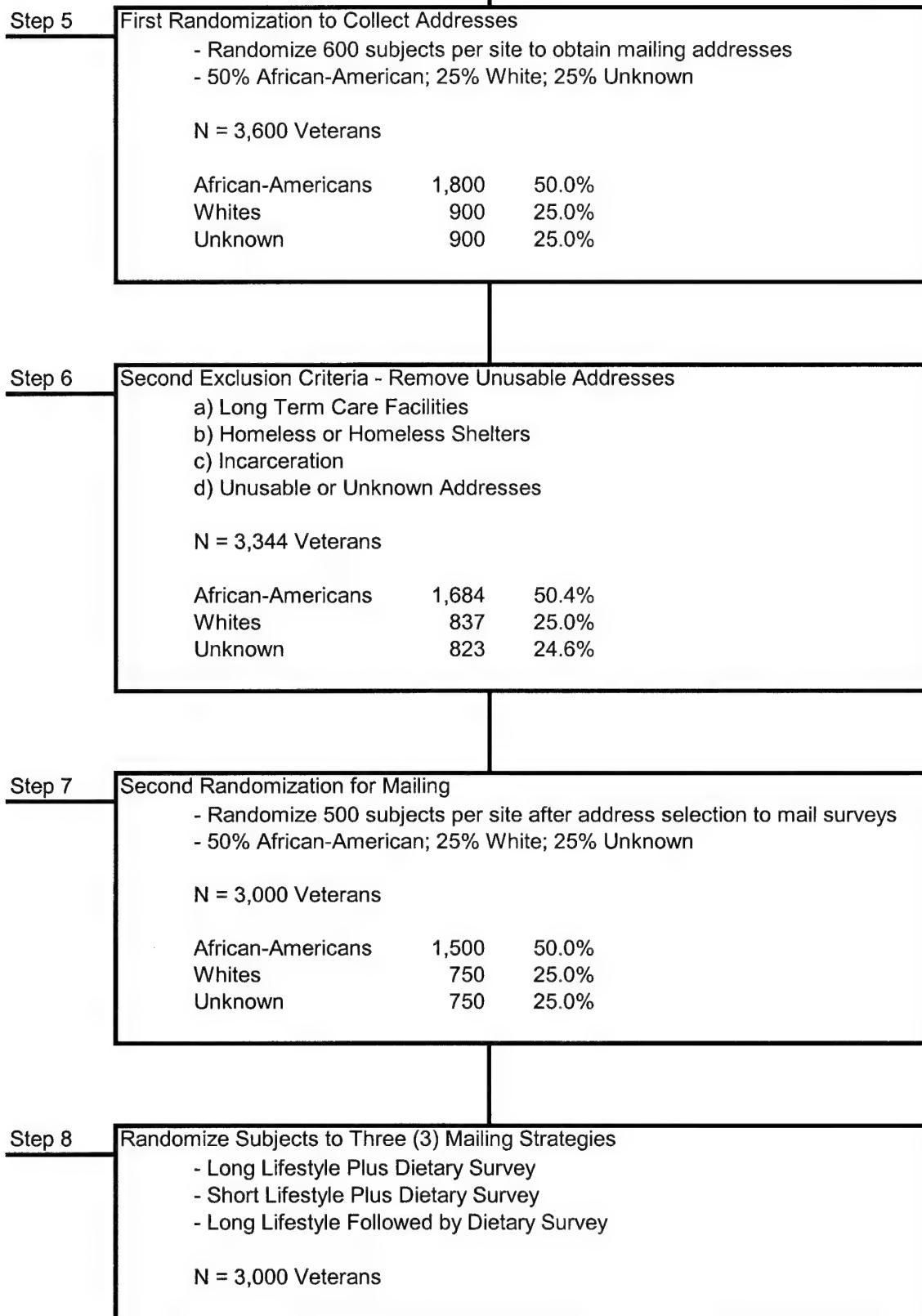
- 1 American Cancer Society. *Cancer facts and figures – 1997*, American Cancer Society, Atlanta, GA, 1997
- 2 Miller BA, Kolonel LN, Bernstein L, Young, Jr. JL, Swanson GM, West D, Key CR, Liff JM. Glover CS, Alexander GA, et al. (Eds). *Racial/ethnic patterns of cancer in the United States 1988-1992*, National Cancer Institute. NIH Pub. No. 96-4104. Bethesda, MD, 1996.
- 3 Kurihara M, Aoki K, Hisamichi S, eds. *Cancer mortality statistics in the world 1950-1985*. Nagoya, Japan: University of Nagoya Press, 1989.
- 4 Pienta KJ, Esper PS. Risk factors for prostate cancer. *Ann Intern Med*. 1993;118:793-803.
- 5 Giovannucci E. Epidemiologic characteristics of prostate cancer. *Cancer*. 1995;75:1766-77.
- 6 Kolonel L. Nutrition and prostate cancer. *Cancer Causes Control*. 1996;7:83-94.
- 7 Mills PK, Beeson WL, Phillips RL, Fraser GE. Cohort study of diet, lifestyle and prostate cancer in Adventist men. *Cancer*. 1989;64:598-604.
- 8 Schuman LM, Mandel JS, Radke A, Seal U, Halberg F. Some selected features of the epidemiology of prostatic cancer: Minneapolis-St. Paul, Minnesota case-control study, 1976-1979. In: Magnus K, ed. *Trends in Cancer Incidence: Causes and Practical Implications*. Washington, DC: Hemisphere Publishing Corp, 1982:345-354.
- 9 Kant A, Block G, Schatzkin A, Zeigler R, Nestle M. Dietary diversity in the US population, NHANES II, 1976-1980. *J Am Diet Assoc*. 1991;91:1526-31.
- 10 Early Stage Prostate Cancer Cohort Study
- 11 Rolnick SJ, Gross CR, Garrard J, Gibson RW. "A Comparison of Response Rate, Data Quality, and Cost in the Collection of Data on Sexual History and Personal Behaviors; Mail Survey Approaches and In-Person Interviews". *American Journal of Epidemiology* 1989 May; 129(5): 1052-61.
- 12 Katz R, Kegles S, Kressin N, Green B, James S. "Willingness to Participate in Biomedical Research: African-Americans vs. Whites". *Annals of Epidemiology*. 2000 Oct 1;10(7): 456-457.
- 13 Green BL, Partridge EE, Fouad MN, Kohler C, Crayton EF, Alexander L. "African-American Attitudes Regarding Cancer Clinical Trials and Research Studies: Results from Focus Group Methodology" *Ethnicity and Disease* 2000 Winter; 10(1): 76-86.
- 14 Shavers VL, Lynch CF, Burmeister LF, "Factors that Influence African-Americans' Willingness to Participate in Medical Research Studies," *Cancer* 2001 Jan 1; 91(S1):233-6.
- 15 Shavers VL, Lynch CF, Burmeister LF, "Knowledge of the Tuskegee Study and its Impact on the Willingness to Participate in Medical Research Studies," *Journal of the National Medical Association* 2000 Dec; 92(12): 563-72.

APPENDICES

- A. Flow Chart of Data Master File**
- B. Lifestyle Surveys (Long and Short)**
- C. Dietary Survey**
- D. Telephone Survey for Non-Responders**
- E. Mailing Material – Core Sample**
 - **Introductory Letter**
 - **Instruction Sheet / Blood Request**
 - **Follow-up Letter**
 - **Consent Form for Survey**
 - **Thank you Letter**
- F. Blood Collection Documents – Core Sample**
 - **Blood Draw Letter**
 - **Blood Lab Directions**
 - **Blood Tracking Form**
 - **Consent Form for Blood Draw**
- G. Face to Face Recruitment Interview**
 - **Face to Face Survey**
 - **Face to Face Introductory Mailing Letter**
 - **Face to Face Follow-up Mailing Letter**
- H. Face to Face Telephone Survey for Non-Responders**
 - **Telephone Survey for Non-Responders – Mailed Survey**
 - **Telephone Survey for Non-Responders – Hand-out Survey**

Appendix A





Appendix B



29384

LIFESTYLE QUESTIONNAIRE

2000

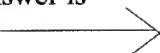
Please use pencil to fill out this questionnaire. Be sure to darken your answer. Do not use a felt tip pen that would bleed through to the opposite side of the paper.

For optimum accuracy, please print carefully and avoid contact with the edges of the box.
The following will serve as an example:

0	1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---	---

Please fill in the boxes with your answer and mark the bubbles to match. For example this answer is marked 123

1	2	3
0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

**Please begin here:**

1. Date of Birth:

--	--	--	--	--	--	--

2. Your current weight (Pounds)

--	--	--

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

3. Your current height

	feet		inches
--	------	--	--------

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

4. What is the highest level of education you have completed?

- Grade school
- High school
- Trade school
- 2 year college
- 4 year college
- Graduate/ professional school

Shade circles like this:

Not like this:



5. What is your major ancestry?

- African-American or Black
- White
- Asian
- American Indian
- Hispanic White
- Other
- Hispanic Black

6. Have you ever heard of a blood test for prostate cancer called PSA (Prostate Specific Antigen) test?

- Yes
- No
- Don't know

7. Have you ever discussed having a PSA test with your doctor?

- Yes
- No
- Don't know

8. Have you ever been told by a doctor or other health care worker that you have or had prostate cancer?

- Yes

- No

Go to #10



If yes when?

Month	Year
<input type="radio"/> Jan	
<input type="radio"/> Feb	0
<input type="radio"/> Mar	1
<input type="radio"/> Apr	2
<input type="radio"/> May	3
<input type="radio"/> June	4
<input type="radio"/> July	5
<input type="radio"/> Aug	6
<input type="radio"/> Sept	7
<input type="radio"/> Oct	8
<input type="radio"/> Nov	9
<input type="radio"/> Dec	

9. If you have or ever had prostate cancer, would you be willing to take part in a different study about prostate cancer?

- Yes
- No

IF YOU HAVE OR EVER HAD PROSTATE CANCER
YOU ARE DONE COMPLETING THIS SURVEY.

PLEASE STOP AND RETURN THE SURVEY IN THE ENVELOPE PROVIDED.

THANK YOU

If you do not have prostate cancer please continue...



PAGE

1

			-				-			
--	--	--	---	--	--	--	---	--	--	--



29384

10a. Have you ever had a blood test for prostate cancer (PSA test)?

Yes No Don't know

↓
If NO, please go to question 11.

10b. Your most recent PSA test result was:

Normal Slightly Elevated Very High

10c. Please fill in your most recent PSA Level if you know it:

--	--

 .

--

 ng/ml

0	0	0	0	0
1	1	1	1	1
2	2	2	2	2
3	3	3	3	3
4	4	4	4	4
5	5	5	5	5
6	6	6	6	6
7	7	7	7	7
8	8	8	8	8
9	9	9	9	9

11. Have you ever had a needle biopsy of the prostate?

Yes No Don't know

12a. Did your father ever have prostate cancer?

Yes No Don't know

↓
If no, skip to question 13a.

12b. If yes, at what age did he learn of it?

Age 50 or younger Age 71-80
 Age 51-60 Age 80 or older
 Age 61-70 Don't know

13a. How many brothers (related by blood, living or dead) do you have?

0 1 2 3 4 5 6+

13b. How many of your brothers have or had prostate cancer?

0 1 2 3 4 5 6+

Don't Know

13c. Did any of your brothers find out they had prostate cancer at age 50 or younger?

Yes No Don't know

14. What was your weight 5 years ago?

--	--	--

 lbs

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

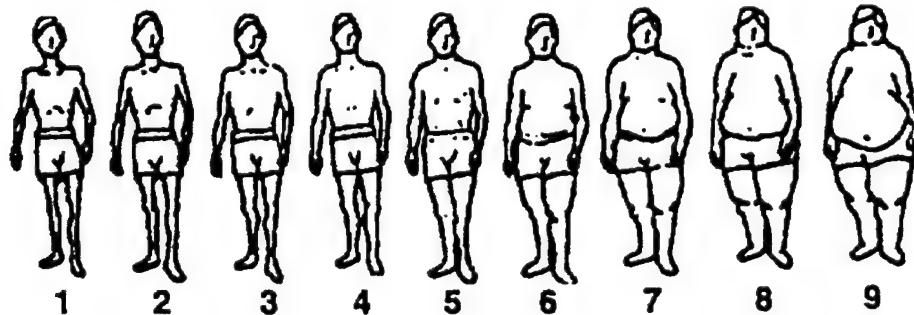
15. What was your weight at age 18?

--	--	--

 lbs

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

16. Which diagram best depicts your body outline at the time indicated?



At age 18? 1 2 3 4 5 6 7 8 9

At age 10? 1 2 3 4 5 6 7 8 9



29384

17a. Do you currently smoke cigarettes? Yes No



17b. Did you smoke in the past? Yes No



17c. How long ago? Less than 30 days

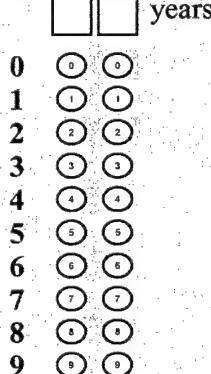
- Between 30 days and 1 year
- 1-2 years
- 3-5 years
- 6-9 years
- 10+ years

17d. On average, when you smoke/ smoked how many packs do you or did you usually smoke?
(1 pack=20 cigarettes)



- Less than 1/2 pack per day
- 1/2 pack per day
- 1 pack per day
- 1 1/2 packs per day
- 2 packs per day
- More than 2 packs per day

17e. For approximately how long have you smoked? years



This section is about your medication use

18. Have you used any of the following medications REGULARLY (at least twice a week)
Please mark all that apply:

Drug Name	No	currently use for less than 3 months	currently use for more than 3 months
Proscar (Finesteride)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Viagra	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
alpha-blockers (such as: Hytrin, Terazosin, Cardura, Prazosin)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

None of the above drugs were ever taken regularly

PAGE

3

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

-

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

-

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



29384

This section is about medical conditions you may have.

19. Has a doctor ever told you that you have or had any of the following?
Please mark all that apply:

High blood pressure

Yes

No

If YES, What YEAR
were you first told?

Diabetes mellitus (High sugar-diabetes)

Yes

No

High cholesterol

Yes

No

High triglycerides

Yes

No

Heart Attack

Yes

No

If yes, were you hospitalized for your heart attack?

Angina pectoris (Heart pain)

Yes

No

If yes, was it confirmed by angiogram (cardiac catheterization)?

Angioplasty (Balloon-PTCA)

Yes

No

Coronary artery bypass graft (CABG)

Yes

No

Stroke (CVA)

Yes

No

Carotid artery surgery (neck artery surgery)

Yes

No

Vasectomy

Yes

No

Surgery for enlarged prostate (e.g., TURP)

Yes

No

Enlarged prostate (Benign Prostatic Hyperplasia, i.e. BPH)

Yes

No

Prostatitis

Yes

No

Syphilis or Gonorrhea

Yes

No

Cancer of colon or rectum

Yes

No

Melanoma (skin cancer)

Yes

No

Lymphoma, leukemia, Hodgkin's disease

Yes

No

Lung cancer

Yes

No

Other cancer

Type: _____

Yes

No

Multiple Sclerosis

Yes

No

Parkinson's Disease

Yes

No

Emphysema, chronic bronchitis, or chronic obstructive pulmonary disease (COPD)

Yes

No

Asthma

Yes

No

Other major illness? 1.

Yes

No

2.

Yes

No

3.

Yes

No



29384

This section is about your family and friends

20. Are you currently married or in a steady relationship?

Yes No

21. Do you have someone that you feel very close to, someone you can share confidences and feelings with?

As much as you want Quite a bit A fair amount A little bit Not at all

22. How many people, including you, live in your household?

1 2 3 4 5 6 7 8 9 10+

23. How often do you go to religious meetings or services?

Never or almost never Less than once per month One to three times per month Once a week More than once a week

24. How many hours *each week* do you participate in groups such as social or work groups, church-connected, self help, support charity, public service or community groups?

None 1-2 Hours 3-5 Hours 6-10 Hours 11-15 Hours 16+ Hours

25. How many close relatives (including children) or close friends do you have?

None Up to 2 hours 3-5 6-9 10+

26. How many close relatives (including children) or close friends do you *SEE* at least once a month?

None 1-2 3-5 6-9 10+

27. How many close relatives (including children) or close friends do you *TALK TO* at least once a month?

None 1-2 3-5 6-9 10+

28. Do you have someone available to help you with errands or chores if you want or need this type of help?

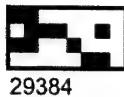
As much as you want Quite a bit A fair amount A little bit Not at all

29. In general, would you say your health is:

Excellent Very good Good Fair Poor

30. Compared to one year ago, how would you rate your health in general now?

Much better now Somewhat better now About the same Somewhat worse than one year ago Much worse now than one year ago



This section is about how you feel about your overall, general health status.

31. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Not Limited At All	Yes Limited A Little	Yes, Limited A Lot
--	--------------------	----------------------	--------------------

Vigorous activities (running, lifting heavy objects, strenuous sports)

Moderate activities (moving a table, pushing a vacuum, bowling, playing golf)

Lifting or carrying groceries

Climbing several flights of stairs

Climbing one flight of stairs

Bending, kneeling, or stooping

Walking more than a mile

Walking several blocks

Walking one block

Bathing or dressing yourself

32. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all Slightly Moderately Quite a bit Extremely

33. During the past 4 weeks, how much bodily pain have you had?

None Very mild Mild Moderate Severe Very severe

34. During the past 4 weeks, how much did pain interfere with your normal work (include work outside the home and housework)?

Not at all Slightly Moderately Quite a bit Extremely

35. During the past 4 weeks, how much of the time ...

	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
--	------------------	----------------------	------------------	------------------------	------------------	-----------------

Did you feel full of pep?

Have you been a very nervous person?

Have you felt so down in the dumps that nothing could cheer you up?

Have you felt calm and peaceful?

Did you have a lot of energy?

Have you felt downhearted and blue?

Did you feel worn out?

Have you been a happy person?

Did you feel tired?



29384

This section is about your activity level within the PAST YEAR

36a. During the past year, what was your average time per week spent doing each of the following activities?

	1-4 none	5-19 min	20-59 min	1-2 hours	2-3 hours	4-6 hours	7-10 hours	11+ hours
--	-------------	-------------	--------------	--------------	--------------	--------------	---------------	--------------

Walking or hiking (including golf and walking to work)

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Jogging (slower than 10 min/mile)

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Running (10 min/mile or faster)

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Calisthenics/ Aerobics/ Rowing Machine/ Treadmill

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Bicycling (includes stationary machine)

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Tennis, Squash, or Racquetball

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Lap swimming

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Weightlifting or Nautilus

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

Other aerobic activity (e.g., heavy outdoor work, raking, pushing a lawn mower, ballroom dancing)

<input type="radio"/>								
-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------	-----------------------

36b. **What is your usual walking pace outdoors?**

- Unable to walk
- Easy, casual (less than 2 mph)
- Normal, average (2 - 2.9 mph)
- Brisk pace (3 - 3.9 mph)
- Very Brisk/striding (4 mph or faster)

36c. **How many flights of stairs (not individual steps) do you climb daily?**

- 2 flights or less
- 3-4 flights
- 5-9 flights
- 10-14 flights
- 15 or more flights

37. **Did someone help you fill out this survey?**

- Yes
- No

38. **Please indicate the name and address of someone at a different address that we might write to in the event that we are unable to contact you.**

First Name: _____

Middle Initial: _____

Last Name: _____

Street: _____

City: _____

State: _____

Zip: _____

Thank you for your participation.

PAGE

7

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	---	----------------------	----------------------	----------------------	---	----------------------	----------------------	----------------------

LIFESTYLE QUESTIONNAIRE

2000

Please use a pencil to fill out this questionnaire. Be sure to darken your answer. Do not use a felt tip pen that would bleed through to the opposite side of the paper.

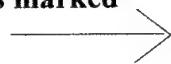
For optimum accuracy, please print carefully and avoid contact with the edges of the box.
The following will serve as an example:

0	1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---	---

Please fill in the boxes with your answer and mark the bubbles to match. For example this answer is marked

123

1	2	3
0	0	0
●	●	●
2	●	2
3	3	●
4	4	4
5	5	5



Please begin here:

1. Date of Birth: / /

2. Your current weight (Pounds)

--	--

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

3. Your current height:

feet inches

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

4. What is the highest level of education you have completed?

- Grade school
- High school
- Trade school
- 2 year college
- 4 year college
- Graduate/professional school

Shade circles like this:

Not like this:



5. What is your major ancestry?

- African-American or Black
- White
- Asian
- American Indian
- Hispanic White
- Other:
- Hispanic Black

6. Have you ever been told by a doctor or other health care worker that you have or had prostate cancer?

Yes No Go to the next page

If yes when?

Month

--	--	--

- Jan
- Feb
- Mar 0
- Apr 1
- May 2
- June 3
- July 4
- Aug 5
- Sept 6
- Oct 7
- Nov 8
- Dec 9

Year

7. If you were diagnosed with prostate cancer, would you be willing to take part in a different study about prostate cancer?

Yes No

IF YOU HAVE OR EVER HAD PROSTATE CANCER YOU ARE DONE COMPLETING THIS SURVEY. PLEASE STOP AND RETURN THE SURVEY IN THE ENVELOPE PROVIDED.
THANK YOU

If you do not have prostate cancer please continue...

PAGE

1

			-				-			
--	--	--	---	--	--	--	---	--	--	--





26953

This section is about how you feel about your overall, general health status.

12. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago Somewhat better now than one year ago About the same as one year ago Somewhat worse than one year ago Much worse now than one year ago

13. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Not Limited At All	Yes Limited A Little	Yes, Limited A Lot
Vigorous activities (running, lifting heavy objects, strenuous sports)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Moderate activities (moving a table, pushing a vacuum, bowling, playing golf)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lifting or carrying groceries	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Climbing several flights of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Climbing one flight of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bending, kneeling, or stooping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking more than a mile	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking several blocks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Walking one block	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bathing or dressing yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

14. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all Slightly Moderately Quite a bit Extremely

15. During the past 4 weeks, how much bodily pain have you had?

None Very mild Mild Moderate Severe Very severe

16. During the past 4 weeks, how much did pain interfere with your normal work (include work outside the home and housework)?

Not at all Slightly Moderately Quite a bit Extremely

17. Did someone help you fill out this survey?

No Yes



26953

18. Please indicate the name and address of someone at a different address that we might write to in the event that we are unable to contact you.

First Name: _____

Middle Initial: _____

Last Name: _____

Street: _____

City: _____

State: _____

Zip: _____

Thank you for your participation.

Appendix C



DIETARY ASSESSMENT



ID NUMBER: _____

DATE: _____



- Darken one circle per question that corresponds to your answer
- Follow arrows

VITAMINS

1. Have you ever regularly taken **multi-vitamins**?

Never have
 Have in the **Past only**



a) For how many years did you take them in the past?

1 year or less 2-4 years 5-9 years 10 or more years

Currently take them



a) If you currently take multi-vitamins, how many do you take per week?

2 or less 3-5 6-9 10 or more

b) If you are currently taking multi-vitamins, for how many years have you been taking them?

1 year or less 2-4 years 5-9 years 10 or more years

c) If you currently take them, what brand do you usually use?

(Specify exact brand and type)

2. Not counting multi-vitamins, have you ever taken any of the following specific vitamins or minerals?

Vitamin A

Never taken
 Taken in the **past only**
 Yes, **currently** take it



Dose per day



How long?

Less than 8,000 IU
 8,000 to 12,000 IU
 13,000 to 22,000 IU
 23,000 IU or more
 Don't know

0-1 year
 2-4 years
 5-9 years
 10 years or more

PLEASE DO NOT WRITE IN THIS AREA



42720

0	1	2	3	4	5	6
0	1	2	3	4	5	6
0	1	2	3	4	5	6
0	1	2	3	4	5	6
0	1	2	3	4	5	6
0	1	2	3	4	5	6
0	1	2	3	4	5	6

MM2-35-097

5	6	7	8	9
5	6	7	8	9
5	6	7	8	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9

0	0	0	0
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
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8	8	8	8
9	9	9	9

2. (Continued) **Not counting multi-vitamins**, have you ever taken any of the following specific vitamins or minerals?

Beta Carotene

Never taken
 Taken in the past only
 Yes, currently take it



Dose per day?

Less than 8,000 IU
 8,000 to 12,000 IU
 13,000 to 22,000 IU
 23,000 IU or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

Vitamin B₆

Never taken
 Taken in the past only
 Yes, currently take it



Dose per day?

Less than 10 mg
 10 to 39 mg
 40 to 79 mg
 80 mg or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

Vitamin C

Never taken
 Taken in the past only
 Yes, currently take it



Dose per day?

Less than 400 mg
 400 to 700 mg
 750 to 1,250 mg
 1,300 mg or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

Vitamin E

Never taken
 Taken in the past only
 Yes, currently take it



Dose per day?

Less than 100 IU
 100 to 250 IU
 300 to 500 IU
 600 IU or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

Selenium

Never taken
 Taken in the past only
 Yes, currently take it



Dose per day?

Less than 80 mcg
 80 to 130 mcg
 140 to 250 mcg
 260 mcg or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

Iron

Never taken
 Taken in the past only
 Yes, currently take it



Dose per day?

mg of elemental iron (325 mg Ferrous Sulfate = 65 mg elemental iron)

Less than 41 mg
 41 to 80 mg
 81 to 150 mg
 151 mg or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

Zinc

Never taken
 Taken in the past only
 Yes, currently take it



Dose per day?

Less than 25 mg
 25 to 74 mg
 75 to 100 mg
 101 mg or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

2. (Continued) **Not counting multi-vitamins**, have you ever taken any of the following specific vitamins or minerals?

**Calcium or Dolomite
(Include Tums)**

Never taken
 Taken in the past only
 Yes, currently take it

Dose per day?

mg of elemental Calcium (1 Tums = 500 mg
Calcium Carbonate = 200 mg elemental.)
 Less than 400 mg
 400 to 900 mg
 901 to 1,300 mg
 1,301 mg or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

**Fish Oil
(Omega 3 fatty acids)**

Never taken
 Taken in the past only
 Yes, currently take it

Dose per day?

Less than 2500 mg
 2500 to 4999 mg
 5000 to 9999 mg
 10,000 mg or more
 Don't know

How long?

0-1 year
 2-4 years
 5-9 years
 10 years or more

Which other supplements are you taking currently on a regular basis (at least once per week)?

None
 Metamucil
 Cod liver oil
 Brewer's yeast
 Vitamin D
 Folic acid or folate (B₉)
 Potassium
 Magnesium
 Niacin
 Other Supplements (specify) _____

DAIRY FOODS

In the following section, please describe how often on average you have used the amount specified in the past year. Please indicate your average total use, taking the portion size into account. For example, if you use 1/2 a glass of milk twice a week, mark 1 glass per week to represent your average total intake.

3. For each food listed, fill in the circle indicating your average total use of the amount specified during the past year.

Skim milk (8 oz. glass)

Never
 Less than once per month
 1-3 glasses per month
 1 glass per week
 2-4 glasses per week
 5-6 glasses per week
 1 glass per day
 2-3 glasses per day
 4 or more glasses per day

1% or 2% milk (8 oz. glass)

Never
 Less than once per month
 1-3 glasses per month
 1 glass per week
 2-4 glasses per week
 5-6 glasses per week
 1 glass per day
 2-3 glasses per day
 4 or more glasses per day

Whole milk (8 oz. glass)

Never
 Less than once per month
 1-3 glasses per month
 1 glass per week
 2-4 glasses per week
 5-6 glasses per week
 1 glass per day
 2-3 glasses per day
 4 or more glasses per day

3. (Continued) Please fill in your average total use, during the past year, of each specified food.

Cream, e.g., in coffee, whipped or sour cream (1 tbs.)

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2 or more tbs. per day

Non-dairy coffee whitener (tsp.)

- Never
- Less than once per month
- 1-3 tsp. per month
- 1 tsp. per week
- 2-4 tsp. per week
- 5-6 tsp. per week
- 1 tsp. per day
- 2 or more tsp. per day

Frozen yogurt, sherbet or non-fat ice cream (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Ice cream (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Flavored yogurt, without Nutrasweet (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2 or more servings per day

Yogurt, plain or with Nutrasweet (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2 or more servings per day

What type of yogurt do you usually eat?

- None
- Regular
- Low fat
- Nonfat

Cottage or ricotta cheese (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Cream cheese (1 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Other cheese, e.g., American, cheddar, etc., plain or as part of a dish (1 slice or 1 oz. serving)

- Never
- Less than once per month
- 1-3 slices per month
- 1 slice per week
- 2-4 slices per week
- 5-6 slices per week
- 1 slice per day
- 2 or more slices per day

What type of cheese do you usually eat?

- None
- Regular
- Low fat or lite
- Nonfat

Butter (small pat or tsp.), added to food or bread; exclude use in cooking

- Never
- Less than once per month
- 1-3 pats per month
- 1 pat per week
- 2-4 pats per week
- 5-6 pats per week
- 1 pat per day
- 2-3 pats per day
- 4 or more pats per day

3. (Continued) Please fill in your average total use, during the past year, of each specified food.

**Margarine (small pat or tsp.),
added to food or bread;
exclude use in cooking**

- Never
- Less than once per month
- 1-3 pats per month
- 1 pat per week
- 2-4 pats per week
- 5-6 pats per week
- 1 pat per day
- 2-3 pats per day
- 4 or more pats per day

**What form of margarine do you usually use? (Do not include
"spray" type margarine)**

None Form? Stick
 Tub
 Squeeze (liquid)

Type? Regular
 Light spread
 Extra light spread
 Nonfat

What specific brand and type (e.g., Land O' Lakes Country Morning Blend Light)?

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

FRUITS

4. Please fill in your average total use, during the past year, of each specified food.

Please try to average your seasonal use of foods over the entire year. For example, if a food such as cantaloupe is eaten 4 times a week during the 3 months that it is in season, then the average total use would be once per week over the year.

**Raisins (1 oz. or small pack)
or grapes**

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Prunes (7 prunes or 1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day

Bananas (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more per day

Cantaloupe (1/4 melon)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2-3 times per day
- 4 or more servings per day

Avocado (1/2 fruit or 1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- One per day
- Two or more per day

Applesauce (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- One or more per day

Fresh apples or pears (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2-3 per day
- 4 or more per day

**Apple juice or cider
(small glass)**

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Oranges (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2-3 per day
- 4 or more per day

4. (Continued) Please fill in your average total use, during the past year, of each specified food.**Orange juice (small glass)**

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Grapefruit (1/2)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2-3 times per day
- 4 or more times per day

Grapefruit juice (small glass)

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Other fruit juices (small glass)

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Strawberries, fresh, frozen or canned (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once or more per day

Blueberries, fresh, frozen or canned (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5 or more servings per week

Peaches, apricots or plums (1 fresh, or 1/2 cup canned)

<input type="radio"/> Never	<input type="radio"/> Once per week
<input type="radio"/> Less than once per month	<input type="radio"/> 2-4 per week
<input type="radio"/> 1-3 per month	<input type="radio"/> 5-6 per week
	<input type="radio"/> 1 or more per day

In summary, how many servings of fruit do you usually eat, not counting juices?

<input type="radio"/> None	<input type="radio"/> 5-6 per week
<input type="radio"/> Less than one per month	<input type="radio"/> 1 per day
<input type="radio"/> 1-3 per month	<input type="radio"/> 2-3 per day
<input type="radio"/> 1 per week	<input type="radio"/> 4-5 per day
<input type="radio"/> 2-4 per week	<input type="radio"/> 6+ per day

VEGETABLES5. Please fill in your average total use, during the past year, of each specified food.**Tomatoes (1)**

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 or more per day

Tomato juice (small glass)

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2 or more glasses per day

**Tomato sauce (1/2 cup)
e.g., spaghetti sauce**

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5 or more servings per week

Salsa, picante or taco sauce (1/4 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Tofu or soybeans (3-4 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

String beans (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5 or more servings per week

5. (Continued) Please fill in your average total use, during the past year, of each specified food.

Broccoli (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Cabbage or cole slaw (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Cauliflower (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Brussels sprouts (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Carrots, raw (1/2 carrot or 2-4 sticks)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Carrots, cooked (1/2 cup) or carrot juice (2-3 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Corn (1 ear or 1/2 cup frozen or canned)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 or more servings per day

Peas or lima beans (1/2 cup fresh, frozen or canned)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Mixed vegetables (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Beans or lentils, baked or dried (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Dark orange (winter) squash (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Eggplant, zucchini or other summer squash (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Yams or sweet potatoes (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Spinach, cooked (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Spinach, raw as in salad

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

5. (Continued) Please fill in your average total use, during the past year, of each specified food.

Kale, mustard, or chard greens (1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Iceberg or head lettuce (serving)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Romaine or leaf lettuce (serving)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Celery (4" stick)

- Never
- Less than once per month
- 1-3 per month
- Once per week
- 2-4 per week
- 5-6 per week
- Once per day
- 2 or more servings per day

Green peppers (3 slices or 1/4 pepper)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Onions as a garnish or in a salad (1 slice)

- Never
- Less than once per month
- 1-3 slices per month
- 1 slice per week
- 2-4 slices per week
- 5-6 slices per week
- 1 or more slices per day

Onions as a vegetable, rings or soup (1 onion)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 or more per day

In summary, how many servings of vegetables do you usually eat, not counting salad or potatoes?

- None
- Less than one per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2-3 per day
- 4-5 per day
- 6+ per day

EGGS, MEAT & FISH

6. Please fill in your average total use, during the past year, of each specified food.

Egg Beaters or egg whites only (1/4 cup or 1 egg)

- Never
- Less than once per month
- 1-3 eggs per month
- 1 egg per week
- 2-4 eggs per week
- 5-6 eggs per week
- 1 egg per day
- 2 or more eggs per day

Eggs whole, with yolk (1)

- Never
- Less than once per month
- 1-3 eggs per month
- 1 egg per week
- 2-4 eggs per week
- 5-6 eggs per week
- 1 egg per day
- 2 or more eggs per day

Bacon (2 slices)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Chicken or turkey sandwich

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5 or more per week

Other chicken or turkey, with skin (4-6 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Other chicken or turkey, without skin (4-6 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Beef or pork hot dogs (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more per day

Chicken or turkey hot dogs (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more per day

Salami, bologna, or other processed meat sandwiches

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5 or more per week

Processed meats, e.g., sausage, kielbasa, etc. (2 oz. or 2 small links)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Hamburger, lean or extra lean (1 patty)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 or more per day

Hamburger, regular (1 patty)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 or more per day

6. (Continued) Please fill in your average total use, during the past year, of each specified food.**Beef, pork, or lamb as a sandwich or mixed dish, e.g., stew, casserole, lasagna, etc.**

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more times per day

Pork as a main dish, e.g., ham or chops (4-6 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more times per day

Beef or lamb as a main dish, e.g., steak, roast (4-6 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more times per day

Liver: beef, calf or pork (4 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2 or more servings per week

Liver: chicken or turkey (1 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2 or more servings per week

Canned tuna fish (3-4 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Breaded fish cakes, pieces, or fish sticks (1 serving, store bought)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more per day

Shrimp, lobster, scallops, clams as a main dish (1 serving)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more times per day

Dark meat fish, e.g., mackerel, salmon, sardines, bluefish, swordfish (3-5 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Other fish, e.g., cod, haddock, halibut (3-5 oz.)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

CEREALS, BREADS & STARCHES

7. Please fill in your average total use, during the past year, of each specified food.

Cold breakfast cereal (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4 or more cups per day

Cooked oatmeal/cooked oat bran (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4 or more cups per day

Other cooked breakfast cereal (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4 or more cups per day

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

What brand and type of cold breakfast cereal do you usually eat? →

Specify brand & type (e.g., "Ralston Rice Chex")

- Don't eat cold breakfast cereal

White bread (slice), including pita bread

- Never
- Less than once per month
- 1-3 slices per month
- 1 slice per week
- 2-4 slices per week
- 5-6 slices per week
- 1 slice per day
- 2-3 slices per day
- 4-5 slices per day
- 6+ slices per day

Dark bread (slice), including wheat pita bread

- Never
- Less than once per month
- 1-3 slices per month
- 1 slice per week
- 2-4 slices per week
- 5-6 slices per week
- 1 slice per day
- 2-3 slices per day
- 4-5 slices per day
- 6+ slices per day

Bagels, English muffins, or rolls (1 whole)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more per day

Muffins (regular) or biscuits (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more per day

Brown rice (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2 or more cups per day

White rice (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2 or more cups per day

7. (Continued) Please fill in your average total use, during the past year, of each specified food.**Pasta, e.g., spaghetti, noodles, etc. (1 cup)**

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2 or more cups per day

Tortillas (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2-3 per day
- 4 or more per day

Other grains, e.g., bulgar, kasha, couscous, etc. (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2 or more cups per day

Pancakes or waffles (3 pieces)

- Never
- Less than once per month
- 1-3 servings per month
- 1 serving per week
- 2-4 servings per week
- 5-6 servings per week
- 1 serving per day
- 2 or more servings per day

French fried potatoes (small order or 1/2 cup)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- 1 or more servings per day

Potatoes, baked, boiled (1) or mashed (1 cup)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more servings per day

Potato chips or corn chips (small bag or 1 oz.)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more servings per day

Crackers, Triscuits, Wheat Thins (5)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2-3 times per day
- 4 or more servings per day

Pizza (2 slices)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

BEVERAGES**CARBONATED BEVERAGES—Consider the serving size as one 12 oz. glass, bottle or can for these carbonated beverages.**8. Please fill in your average total use, during the past year, of each specified food.**LOW-CALORIE (Sugar-free types)****Low-calorie cola, e.g., Diet Coke with caffeine (1 glass, bottle, can)**

- Never
- Less than once per month
- 1-3 cans per month
- 1 can per week
- 2-4 cans per week
- 5-6 cans per week
- 1 can per day
- 2-3 cans per day
- 4 or more cans per day

Low-calorie caffeine-free soda (1 glass, bottle, can)

- Never
- Less than once per month
- 1-3 cans per month
- 1 can per week
- 2-4 cans per week
- 5-6 cans per week
- 1 can per day
- 2-3 cans per day
- 4 or more cans per day

Other low-calorie carbonated beverage, e.g., Diet 7-Up, Fresca, diet ginger ale (1 glass, bottle, can)

- Never
- Less than once per month
- 1-3 cans per month
- 1 can per week
- 2-4 cans per week
- 5-6 cans per week
- 1 can per day
- 2-3 cans per day
- 4 or more cans per day

8. (Continued) Please fill in your average total use, during the past year, of each specified food.

REGULAR TYPES (not sugar-free)

**Coke, Pepsi, or other
cola with sugar (1 glass,
bottle, can)**

- Never
- Less than once per month
- 1-3 cans per month
- 1 can per week
- 2-4 cans per week
- 5-6 cans per week
- 1 can per day
- 2-3 cans per day
- 4 or more cans per day

**Caffeine-Free Coke, Pepsi,
or other cola with sugar
(1 glass, bottle, can)**

- Never
- Less than once per month
- 1-3 cans per month
- 1 can per week
- 2-4 cans per week
- 5-6 cans per week
- 1 can per day
- 2-3 cans per day
- 4 or more cans per day

**Other carbonated beverage
with sugar, e.g., 7-Up
(1 glass, bottle, can)**

- Never
- Less than once per month
- 1-3 cans per month
- 1 can per week
- 2-4 cans per week
- 5-6 cans per week
- 1 can per day
- 2-3 cans per day
- 4 or more cans per day

OTHER BEVERAGES

**Hawaiian Punch, lemonade,
or other non-carbonated fruit
drinks (1 glass, bottle, can)**

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2-3 glasses per day
- 4 or more glasses per day

**Beer, regular
(1 glass, bottle, can)**

- Never
- Less than once per month
- 1-3 cans per month
- 1 can per week
- 2-4 cans per week
- 5-6 cans per week
- 1 can per day
- 2-3 cans per day
- 4-5 cans per day
- 6+ cans per day

**Light beer, e.g., Bud Light
(1 glass, bottle, can)**

- Never
- Less than once per month
- 1-3 cans per month
- 1 can per week
- 2-4 cans per week
- 5-6 cans per week
- 1 can per day
- 2-3 cans per day
- 4-5 cans per day
- 6+ cans per day

Red wine (4 oz. glass)

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2-3 glasses per day
- 4-5 glasses per day
- 6+ glasses per day

White wine (4 oz. glass)

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2-3 glasses per day
- 4-5 glasses per day
- 6+ glasses per day

**Liquor, e.g., whiskey, gin,
etc. (1 drink or shot)**

- Never
- Less than once per month
- 1-3 drinks per month
- 1 drink per week
- 2-4 drinks per week
- 5-6 drinks per week
- 1 drink per day
- 2-3 drinks per day
- 4-5 drinks per day
- 6+ drinks per day

8. (Continued) Please fill in your average total use, during the past year, of each specified food.**Plain water, bottled or tap including mineral water and soda water (1 cup or glass)**

- Never
- Less than once per month
- 1-3 glasses per month
- 1 glass per week
- 2-4 glasses per week
- 5-6 glasses per week
- 1 glass per day
- 2-3 glasses per day
- 4-5 glasses per day
- 6+ glasses per day

Herbal tea (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4-5 cups per day
- 6+ cups per day

Tea (1 cup), Not herbal teas

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4-5 cups per day
- 6+ cups per day

Decaffeinated coffee (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4-5 cups per day
- 6+ cups per day

Coffee with caffeine (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2-3 cups per day
- 4-5 cups per day
- 6+ cups per day

SWEETS, BAKED GOODS & MISCELLANEOUS9. Please fill in your average total use, during the past year, of each specified food.**Pure chocolate candy bar or packet, (e.g., Hershey's, M&M's)**

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2-3 per day
- 4 or more per day

Other mixed candy bars, (e.g., Snickers, Milky Way, Reeses)

- Never
- Less than once per month
- 1-3 candy bars per month
- 1 candy bar per week
- 2-4 candy bars per week
- 5-6 candy bars per week
- 1 candy bar per day
- 2-3 candy bars per day
- 4 or more candy bars per day

Candy without chocolate (e.g., 1 pack mints, Lifesavers)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2-3 times per day
- 4 or more times per day

Jams, jellies, preserves, syrup, or honey (1 tbs.)

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2-3 tbs. per day
- 4 or more tbs. per day

Peanut butter (1 tbs.)

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2-3 tbs. per day
- 4 or more tbs. per day

Popcorn (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 cup per day
- 2 or more cups per day

9. (Continued) Please fill in your average total use, during the past year, of each specified food.

Pretzels (1 oz., or small bag)

- Never
- Less than once per month
- 1-3 servings per month
- One serving per week
- 2-4 servings per week
- 5-6 servings per week
- One serving per day
- 2 or more servings per day

Cookies, home baked (1)

- Never
- Less than once per month
- 1-3 cookies per month
- 1 cookie per week
- 2-4 cookies per week
- 5-6 cookies per week
- 1 cookie per day
- 2-3 cookies per day
- 4 or more cookies per day

Cookies, ready made (1)

- Never
- Less than once per month
- 1-3 cookies per month
- 1 cookie per week
- 2-4 cookies per week
- 5-6 cookies per week
- 1 cookie per day
- 2-3 cookies per day
- 4 or more cookies per day

Brownies (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more per day

Doughnuts (1)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2-3 per day
- 4 or more per day

Cake, home baked (slice)

- Never
- Less than once per month
- 1-3 slices per month
- 1 slice per week
- 2-4 slices per week
- 5-6 slices per week
- 1 or more slices per day

Cake, ready made (slice)

- Never
- Less than once per month
- 1-3 slices per month
- 1 slice per week
- 2-4 slices per week
- 5-6 slices per week
- 1 or more slices per day

Pie, homemade (slice)

- Never
- Less than once per month
- 1-3 slices per month
- 1 slice per week
- 2-4 slices per week
- 5-6 slices per week
- 1 or more slices per day

Pie, ready made (slice)

- Never
- Less than once per month
- 1-3 slices per month
- 1 slice per week
- 2-4 slices per week
- 5-6 slices per week
- 1 or more slices per day

Sweet roll, coffee cake or other pastry, home baked (serving)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Sweet roll, coffee cake or other pastry, ready made (serving)

- Never
- Less than once per month
- 1-3 times per month
- Once per week
- 2-4 times per week
- 5-6 times per week
- Once per day
- 2 or more servings per day

Peanuts (small packet or 1 oz.)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more servings per day

Other nuts (small packet or 1 oz.)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2 or more servings per day

Oat bran, added to food (1 tbs.)

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2 or more servings per day

Other bran, added to food (1 tbs.)

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2 or more servings per day

9. (Continued) Please fill in your average total use, during the past year, of each specified food.**Wheat germ (1 tbs.)**

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2 or more servings per day

Chowder or cream soup (1 cup)

- Never
- Less than once per month
- 1-3 cups per month
- 1 cup per week
- 2-4 cups per week
- 5-6 cups per week
- 1 or more cups per day

Ketchup or red chili sauce (1 tbs.)

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2 or more servings per day

Salt added at table (1 shake)

- Never
- Less than once per month
- 1-3 shakes per month
- 1 shake per week
- 2-4 shakes per week
- 5-6 shakes per week
- 1 shake per day
- 2-3 shakes per day
- 4-5 shakes per day
- 6+ shakes per day

How many teaspoons of sugar do you add to your beverages or food each day?

Teaspoons

Nutrasweet or Equal (1 packet) NOT Sweet 'N Low

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2-3 per day
- 4-5 per day
- 6+ per day

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

Garlic (1 clove or 4 shakes)

- Never
- Less than once per month
- 1-3 per month
- 1 per week
- 2-4 per week
- 5-6 per week
- 1 per day
- 2-3 per day
- 4-5 per day
- 6+ per day

Low fat mayonnaise/fat free mayonnaise (2 tbs.)

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2 or more tbs. per day

Regular mayonnaise (2 tbs.)

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2 or more tbs. per day

Salad dressing (2 tbs.) →

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2-3 tbs. per day
- 4 or more tbs. per day

Type of salad dressing:

- Nonfat
- Low fat
- Olive oil dressing
- Regular

Olive oil added to food or bread (1 tbs.); exclude use in cooking

- Never
- Less than once per month
- 1-3 tbs. per month
- 1 tbs. per week
- 2-4 tbs. per week
- 5-6 tbs. per week
- 1 tbs. per day
- 2-3 tbs. per day
- 4-5 tbs. per day
- 6+ tbs. per day

10. How much of the visible fat on your beef, pork or lamb do you remove before eating?

- Don't eat meat
- Remove all visible fat
- Remove most
- Remove small part of fat
- Remove none

11. What kind of fat is usually used for frying and sautéing at home?

- Don't fry
- Real butter
- Margarine
- Olive oil
- Vegetable oil
- Vegetable shortening
- Lard/bacon fat
- Pam type spray

12. What kind of fat is usually used for baking at home?

- Don't bake
- Real butter
- Margarine
- Olive oil
- Vegetable oil
- Vegetable shortening
- Lard/bacon fat
- Pam type spray

13. How often do you eat food fried, stir-fried in oil, or sautéed at home?

- Never
- Less than once a week
- Once per week
- 2-4 times per week
- 5-6 times per week
- Daily

15. What type of cooking oil is usually used at home (e.g., Wesson Corn Oil)?

(Specify brand and type)

16. Are there any other foods not mentioned above that you usually eat at least once per week?

Include for example: Paté, cream sauce, custard, radishes, fava beans, coconut, mango, horseradish, parsnips, rhubarb, papaya, dried apricots, dates, figs. (Do not include dry spices and do not list something that has been listed in the previous sections.)

Other foods that you usually eat at least once per week	Usual serving size	Servings per week
(a)		
(b)		
(c)		

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9
10	11	12
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98	99	100

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92	93	94
93	94	95
94	95	96
95	96	97
96	97	98
97	98	99
98	99	100

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9
10	11	12
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59	60	61
60	61	62
61	62	63
62	63	64
63	64	65
64	65	66
65	66	67
66	67	68
67	68	69

DIET CHANGES

17. Do you currently follow a special diet?

No
 Yes → Physician prescribed
 Self prescribed

a) If yes, for how many years?

(Number of years on diet)

17	
a	
0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9
	b
0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

b) If yes, what kind of diet do you follow?

(Select more than one if necessary.)

Weight reduction (low calorie)
 Low cholesterol
 Low sodium
 Diabetic
 Low fat
 Low triglyceride
 Ulcer
 High Potassium

 Other →

(Specify type of diet)

18. How has your use of the following foods and beverages changed over the PAST TEN YEARS?

Whole milk

Use has decreased
 Use about the same
 Use has increased

Butter

Use has decreased
 Use about the same
 Use has increased

Margarine

Use has decreased
 Use about the same
 Use has increased

Eggs

Use has decreased
 Use about the same
 Use has increased

Fish

Use has decreased
 Use about the same
 Use has increased

Red meat

Use has decreased
 Use about the same
 Use has increased

Fruits

Use has decreased
 Use about the same
 Use has increased

Vegetables

Use has decreased
 Use about the same
 Use has increased

Whole wheat bread

Use has decreased
 Use about the same
 Use has increased

Whole grains

Use has decreased
 Use about the same
 Use has increased

Sugar

Use has decreased
 Use about the same
 Use has increased

Alcohol

Use has decreased
 Use about the same
 Use has increased

Thank you!

**Please check to make sure you have not
accidentally skipped any pages.**

PLEASE DO NOT WRITE IN THIS AREA



42720

Appendix D



18117

Subject ID:

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Name: _____

Alternate Area Code: _____ Phone Number: _____

Race: _____

First Attempt:Date:

--	--

 /

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 /

--	--	--	--	--

 Time:

--	--

 :

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 Military TimeInterviewer: Caterina Bob Peter Margaret Stanley PennyResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

Second Attempt:Date:

--	--

 /

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 /

--	--	--	--	--	--

 Time:

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 Military TimeInterviewer: Caterina Bob Peter Margaret Stanley PennyResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

Third Attempt:Date:

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 Time:

--	--

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 Military TimeInterviewer: Caterina Bob Peter Margaret Stanley PennyResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

1. Successful Interview (part 2)	7. Wrong Number
2. Doesn't Recall/ did not receive survey (part 3)	8. Phone Disconnected
3. Unwilling to Participate	9. Other (describe in comment)
4. Unable to Participate due to health reasons	10. Prostate Cancer
5. No Answer/ busy	11. Completed Survey
6. Left message	



18117

Subject ID:

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"Hi this is _____ . I'm a (nurse, health researcher, other) with the Prostate Disease Project at the VA Medical Center in Boston."

"May I speak with Mr. _____ .

If not home, ask for a time that is good for the participant _____

Repeat introductory phrase if participant is called to the phone. Otherwise continue ...

"We recently sent you a package with two questionnaires. The questionnaires asked about your diet, physical activity, medication use, and smoking."

1) "Did you receive these questionnaires?" (Describe questionnaires to participant if they can't recall: "The questionnaires were initially sent in _____ in a large manila envelope. One questionnaire was green (groups 1 and 3)/ yellow (group 2) the other was pink (group 1 and 2.) A second copy was sent over a week ago."

Yes → **If YES, Go to Part 2**

No → **If NO, "Can I verify your address?"**

2) Check participant's address:

OLD:

NEW:

--

Has the address changed?

No → **IF NO, Go to Part 3**

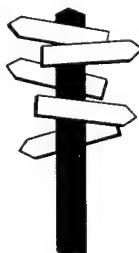
Yes → **IF YES,**

3) "Would you be willing to complete these questionnaires if we sent you a copy to your new address?"

No → **IF NO, Go to Part 3**

Yes → **IF YES, Mail survey...**

"We appreciate your participation in our prostate cancer project. The results will help our efforts to prevent and treat prostate cancer."





Subject ID:

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Phone Questionnaire Part 2

1) "We are trying to learn the best way we can collect this information. It's helpful to know why people did not respond so we can improve our survey. Can we ask you a few questions about why you did not respond? It should take about ten minutes."

Yes

No → **IF NO, "Is this a bad time? Is there a better time we can call?"**

If participant is unwilling to participate - "
Thank You for your time. Goodbye."



IF YES, "Thank You."

"First of all we would like to ask a few questions about prostate cancer."

2) "Have you ever had prostate cancer?"

Yes → **IF YES, "When were you told that you had prostate cancer?"**

No

_____ (Try to obtain month and year)

**If the participant had prostate cancer, then
discontinue the survey.**

*"This is all the information we need.
Thank You for your participation."*



IF NO, "I would like to ask you some 'yes/no' type questions about the survey we sent."

3) "Were you unable to read this questionnaire due to limitations in sight?"

Yes → **If YES, go to Question 16**

No



18117

Subject ID:

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4) *"Did you have difficulties understanding the cover letter or instruction sheet?"*

 Yes No

5) *"Did the questionnaires look too long?"*

 Yes No

6) *"Did you have difficulties understanding the questions in the survey?"*

 Yes No

7) *"Did you not have time to complete the questionnaires?"*

 Yes No

8) *"Did you not feel well enough to answer the questions?"*

 Yes No

9) *"Did you feel there were too many questions to answer?"*

 Yes No

10) *"Did you have difficulties recalling details asked in the questions?"*

For example did you have difficulties recalling your diet, medical treatments, vitamin use, PSA levels?"

 Yes No

11) *"Were you concerned about the confidentiality of your responses?"*

 Yes No

12) *"Did you find the questions too sensitive to answer?"*

 Yes No

13) *"Did past experience with the VA influence your decision to complete these questionnaires?"*

 Yes No

14) *"Do you choose not to participate in any research projects?"*

 Yes No

15) *"Do you wish to share with us any other reasons for not completing the questionnaires?"*

 Yes No

Participants may spend a lot of time with this question. If so, redirect them to the next set of questions.



Subject ID:

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16) "Do you receive your usual care from the VA?" Yes No

17) "Have you had positive experiences with the health care that you've received from the VA in the past 3 months?" Yes No

Comments: _____

18) "Have you participated in VA research projects including completing surveys in the past?"

No

Yes

→ IF YES,

"Have you had good or bad experiences participating in research projects?"

GOOD

BAD

NO OPINION

Comments: _____

19) "Do you think medical research helps veterans get better care?" Yes No

20) "Do you think prostate cancer is an important health care issue?" YES

NO

DON'T KNOW

21) "Would you mind identifying the highest level of education you have completed?"

(List categories to the participants) →

- Grade School
- High School
- Trade School
- 2 year college
- 4 year college
- Graduate/professional school
- Participant refused to identify education

Subject ID:

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22) "Would you mind identifying your race?"
(List categories to the participants)

- Asian
- Hispanic White
- Hispanic Black
- White
- American Indian
- African-American or Black
- Other: _____
- refused to respond

If African-American (based on self-reported race):

22a) "Is prostate cancer a serious problem for the African-American community?"

- YES
- NO
- DON'T KNOW

22b) "Do you think research on prostate cancer helps African Americans?"

- YES
- NO
- DON'T KNOW

23) "Would you have been willing to participate if the survey was offered in a personal face to face interview?"

- Yes
- No

"Thank you for participating.
This information will be helpful to future health care studies.

Thanks again
Goodbye"





Subject ID:

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Phone Questionnaire Part 3

1) "We are trying to learn the best way we can collect health information. Can we ask you a few questions? It should take about ten minutes."

Yes

No → **IF NO, "Is this a bad time? Is there a better time we can call?"**

If participant is unwilling to participate - "
Thank You for your time. Goodbye.



IF YES, "Thank You."

"First of all we would like to ask a few questions about prostate cancer."

2) "Were you ever told by a doctor that you had prostate cancer or were you told in the past?"

Yes



IF YES, "When were you told that you had prostate cancer?"

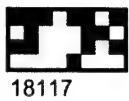
No

(Try to obtain month and year)

**If the participant had prostate cancer, then
discontinue the survey.**

*"This is all the information we need.
Thank You for your participation."*





18117

Subject ID:

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3) "Do you receive your usual care from the VA?" Yes No4) "Have you had positive experiences with the health care that you've received from the VA in the past 3 months?" Yes No

Comments:

5) "Have you participated in VA research projects including completing surveys in the past?"

 No Yes → IF YES,

"Have you had good or bad experiences participating in research projects?"

 GOOD BAD NO OPINION

Comments:

6) "Do you think medical research helps veterans get better care?" Yes No7) "Do you think prostate cancer is an important health care issue?" YES NO DON'T KNOW

8) "Would you mind identifying the highest level of education you have completed?"

(List categories to the participants) →

- Grade School
- High School
- Trade School
- 2 year college
- 4 year college
- Graduate/professional school
- Participant refused to identify education



18117

Subject ID:

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9) "Would you mind identifying your race?"

(List categories to the participants)

- Asian
- Hispanic White
- Hispanic Black
- White
- American Indian
- African-American or Black
- Other: _____
- refused to respond

**If African-American:**

9a) Is prostate cancer a serious problem for the African-American community?

- YES
- NO
- DON'T KNOW

9b) Do you think research on prostate cancer helps African Americans?

- YES
- NO
- DON'T KNOW

10) If you had received the survey, would you have completed it? Yes No11) Would you have been willing to participate if the survey was offered over the telephone? Yes No12) Would you have been willing to participate if the survey was offered in a personal face to face interview? Yes No

"Thank you for participating.
This information will be helpful to future health care studies.

Thanks again
Goodbye"



Appendix E



MAVERIC

MASSACHUSETTS VETERANS EPIDEMIOLOGY
RESEARCH AND INFORMATION CENTER



Harvard



Medical School
School of Public Health

Boston University



School of Medicine
School of Public Health

October 30, 2000

Dear Veteran,

We are writing to ask for your help in a scientific study run by the VA through the Massachusetts Veterans Epidemiological Research Information Center (MAVERIC) with the help of researchers at Harvard University, Boston University, the Baltimore VAMC, and the Department of Defense. We are trying to learn how diet and lifestyle are related to the development of prostate cancer.

We are interested in enrolling men who do not have prostate cancer. Prostate cancer is one of the most common diseases in the United States. Approximately 180,000 men will develop prostate cancer this year and 40,000 men will die from the disease. Rates for prostate cancer are even higher in African-American men. This is a serious health problem in our country. The causes of prostate cancer are mostly unknown. By giving us some information about yourself, we can learn more about the factors related to prostate cancer in hopes of better treating veterans with this disease.

To participate, please complete the enclosed consent and questionnaire by following the instructions attached to this letter. You will be asked to provide blood for our research to determine biochemical and genetic risk factors for prostate cancer. This is not a requirement to participate. If you do not wish to give blood, you will still be a valued member of our study. You will also be contacted to complete additional questionnaires in the future.

Your name was obtained, in confidence, from VA patient files. The VA Research Review Board has reviewed this project and supports this work. Your participation is completely voluntary. However, the success of the research critically depends on the cooperation of men invited to participate. The information you provide will only be used for research purposes. It will not be shared outside of the study and will be kept in the strictest medical confidence. No personal data will be released to the public.

With full participation, we are confident that we will find ways to better understand the development of prostate cancer. By participating, you will be making a key contribution to men's health. Please call us at the Prostate Cancer Center phone line (1-800-367-0677) if you have any questions.

Sincerely yours,

Steven Wright, Ph.D.
VA Boston Healthcare System

Douglas Bradham, DrPH
Baltimore VAMC

INSTRUCTIONS

To participate in this study, we would like you to sign the consent form and fill out the enclosed surveys. One survey is on diet and the other asks about medical conditions, physical activity, and your lifestyle.

- First, read the consent form explaining the purpose of our study. Sign with a **PEN** and date the back of the form.
- Complete both surveys with a No. 2 pencil (one is enclosed). The surveys should take less than an hour to complete.
- If you have any questions about the surveys, please call the MAVERIC Prostate Cancer Study at 1-800-367-0677.
- Once you complete the surveys, please check the pages to make sure none of them were accidentally skipped.
- Send this page, the surveys, and the consent form to the MAVERIC Prostate Cancer Study in the self-addressed envelope enclosed in this package.

In the future, we will send you additional surveys about your health and diet. These surveys will be sent to you once every two years by our research center.

Thank you for taking the time to complete the surveys.

Would you be willing to provide a blood sample for our research?

{Optional Request – Please Answer Below}

YES

NO



MAVERIC

MASSACHUSETTS VETERANS EPIDEMIOLOGY
RESEARCH AND INFORMATION CENTER



Harvard



Medical School
School of Public Health

Boston University



School of Medicine
School of Public Health

December 27, 2000

Dear Veteran,

We recently sent you a letter requesting your participation in a scientific study about prostate cancer. This study is being run by the VA through the Massachusetts Veterans Epidemiological Research Information Center (MAVERIC) with the help of researchers at the Baltimore VAMC, Harvard University, Boston University, and the Department of Defense. We are sending this information again with the hope that you are willing to take part at this time. If you have already responded to our survey, please disregard this notice.

We are interested in enrolling men who do not have prostate cancer. Prostate cancer is one of the most common diseases in the United States. Approximately 180,000 men will develop prostate cancer this year and 40,000 men will die from the disease. Rates for prostate cancer are even higher in African-American men. This is a serious health problem in our country. The causes of prostate cancer are mostly unknown. By giving us some information about yourself, we can learn more about the factors related to prostate cancer in hopes of better treating veterans with this disease.

To participate, please complete the enclosed consent and questionnaire by following the instructions attached to this letter. The questionnaires take approximately one hour to complete. You will be asked to provide a small sample of blood for our research to learn more about biochemical and genetic risk factors for prostate cancer. This is not a requirement to participate. If you do not wish to give blood, you will still be a valued member of our study. You will also be contacted to complete additional questionnaires in the future.

Your name was obtained, in confidence, from VA patient files. Your participation is completely voluntary. If you decide not to participate, your current or future care at the VA will not be affected. The information you provide will only be used for research purposes. It will not be shared outside of the study and will be kept in the strictest medical confidence. No personal data will be released to the public.

We are hopeful that we will find ways to better understand the development of prostate cancer. By participating you will be making a key contribution to men's health. Please call us at the Prostate Cancer Center phone line (1-800-367-0677) if you have any questions.

Sincerely yours,

Steven Wright, Ph.D.
VA Boston Healthcare System

Douglas Bradham, DrPH
Baltimore VAMC

VA Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ Date: _____

Title of Study: Risk Factors for Prostate CancerPrincipal Investigator: Dr. Douglas Bradham VAMC: Baltimore**PURPOSE**

The purpose of this research study is to examine factors that may be associated with the diagnosis of Prostate Cancer. There is some evidence that diet and lifestyle may be connected to this disease. This study will be conducted at the Baltimore VA Medical Center in conjunction with the Department of Defense. It will involve patients who do not have Prostate Cancer.

PROCEDURES

If you agree to participate in this study, you will respond to two detailed questionnaires, which will ask about your age, race, medical history, diet, and lifestyle. Both questionnaires should take no more than one hour to complete.

DISCOMFORTS AND INCONVENIENCE

There are no perceived discomforts or known physical risks from this study.

RISKS

No risks to the patient are anticipated.

BENEFITS

You may not be helped personally by taking part in this study, but your participation may lead to knowledge that will help others. This study will generate information to help us improve high blood pressure control.

OTHER TREATMENT AVAILABLE

Your treatment at the VA will not be any different if you participate in the study. No treatment is provided as a part of this study. You can withdraw from this project at any time. Withdrawal will not affect your opportunity to obtain treatment at the VA Medical Center or any other benefits to which you are entitled. Likewise, your refusal to participate in this project will not affect your opportunity to obtain treatment at this VA Medical Center or any other benefits to which you are entitled.

SUBJECT'S IDENTIFICATION (I.D. plate or give name - last, first, middle)



VA Department of Veterans Affairs

VA RESEARCH CONSENT FORM

(Continuation Page 2)

Subject Name: _____ Date: _____

Title of Study: Risk Factors for Prostate CancerPrincipal Investigator: Dr. Douglas Bradham VAMC: Baltimore**RESEARCH RESULTS**

The results of this study may identify factors related to Prostate Cancer and may suggest ways to improve treatment of this disease. Any new information that we learn during the course of this study will be submitted for publication in journals that are read by other researchers in the field of Prostate Cancer.

1. All research records, including interviews, will be in the care of Dr. Wright. They will be safeguarded under lock and key at the VA Boston Healthcare System, West Roxbury, Massachusetts. No one else except the study investigators will have access to these records. They will be destroyed at the end of the study in accordance with standard research practices for destroying study-related material.
2. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your medical records will be maintained according to this medical center's requirements.

SPECIAL INFORMATION

1. You are not required to take part in this study: your participation is entirely voluntary.
2. You can refuse to participate now or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment, if you are a patient.
3. There will be no costs to you for any of the treatment or testing done as part of this research study.
4. Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.



UNIVERSITY STATEMENT: The University is committed to providing subjects of its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

The research described in this consent form has been classified as minimal risk by the University of Maryland Institutional Review Board (IRB), a group of scientists, physicians, and other experts. The Board's membership includes persons who are not affiliated with the University and persons who do not conduct research projects. The Board's decision that the research is minimal risk does not mean that the research is risk-free, however. Generally speaking, you are assuming the risks of research participation.

VA Department of Veterans Affairs

VA RESEARCH CONSENT FORM

(Continuation Page 3)

Subject Name: _____ Date: _____

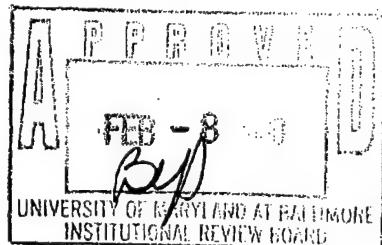
Title of Study: Risk Factors for Prostate CancerPrincipal Investigator: Dr. Douglas Bradham VAMC: Baltimore

as discussed in the consent form. But, if you are harmed as a result of the negligence of a research, you can make a claim for compensation. If you believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact the IRB for more information about claims procedures.

Institutional Review Board
 University of Maryland
 655 West Baltimore Street, #BRB-14-016
 Baltimore, Maryland 21201
 (410-706-5037)

If you agree to join this study, please sign your name below.

**NOT VALID WITHOUT THE
 IRB STAMP OF CERTIFICATION**



VALID FROM 2-8-00 TO 2-701

Subject's signature

I have read and understand the information on this form.

I have had the information on this form explained to me.

Witness to Consent procedures*

RPN
 NO. 1199028

Signature of Investigator

Date: _____

*Optional unless subject is illiterate or unable to sign.

NOTE: Copies of this Consent Form with original signatures **must** be a) retained on file by the Principal Investigator; and b) given to the subject. A copy must also be deposited in the patient's medical record (if any).



MAVERIC

MASSACHUSETTS VETERANS EPIDEMIOLOGY
RESEARCH AND INFORMATION CENTER



Harvard

Boston University



Medical School
School of Public Health



School of Medicine
School of Public Health

October 6, 2000

«FNAME» «MNAME» «LNAME»
«ADRS1»
«ADRS2»
«CITY», «STATE» «ZIP»

Dear MR. «LNAME»,

Thank you for your response to our health and dietary surveys earlier this year. Your support in our prostate health study is greatly appreciated by the Veterans Administration and our researchers (Massachusetts VA Medical Epidemiological Research Information Center, the Baltimore VAMC, Harvard University, Boston University, and the Department of Defense). With this information we will better understand the development of prostate cancer and aim to discover new ways to prevent the disease.

The information you provide will only be used for research purposes. It will not be shared outside of the study and will be kept in the strictest medical confidence. No personal data will be released to the public. You will also be contacted to complete additional questionnaires in the future.

Attached is a copy of the consent form you signed when you completed the survey. This is your documentation that you have taken part in our research study. A copy will be included with your medical records at your local VA.

Thank you for your support in this project. By participating, you will be making an important contribution to men's health and prostate cancer prevention. If you have any questions or comments about our study, please give us a call at 1-800-367-0677.

Sincerely yours,

Steven Wright, Ph.D.
VA Boston Healthcare System

Douglas Bradham, DrPH
Baltimore VAMC

Appendix F



MAVERIC

MASSACHUSETTS VETERANS EPIDEMIOLOGY
RESEARCH AND INFORMATION CENTER



Harvard



Medical School
School of Public Health

Boston University



School of Medicine
School of Public Health

February 17, 2000

Dear Veteran,

Thank you for responding to our prostate cancer surveys. Your participation is greatly appreciated by the staff of the VA Prostate Cancer Study. With this information we hope to better understand prostate cancer and to find ways to prevent the disease.

You indicated that you were willing to provide a sample of blood for our research. The blood samples collected will be stored and later used to help us identify important risk factors for prostate cancer.

You may give blood without an appointment or you may give blood as part of a scheduled appointment. We have enclosed directions to the blood drawing area at your local VA Medical Center.

Please bring the brightly colored envelope with you when you give blood. The envelope contains all the necessary information for the attendant to draw your blood. Included in this envelope is a copy of the Patient Consent Form. This is a standard form required for all VA research studies that is designed to protect you from any problems that might arise from drawing blood. The consent form outlines the responsibilities of the VA, emergency contacts, and details about why we need blood for this project. You will be asked to read the consent form and sign the last page before you give blood.

If you have any questions or concerns please feel free to contact us at the Prostate Cancer Study 1-800-367-0677. We will be happy to discuss any issues concerning this project with you. Thank you again for your support with this VA study.

Sincerely,

Steven Wright, Ph.D.
VA Boston Healthcare System

Douglas Bradham, DrPH
Baltimore VAMC

INSTRUCTIONS FOR GIVING BLOOD AT THE BALTIMORE VAMC

If possible please fast 12 hours before giving blood.

You may give blood at the Baltimore VAMC blood lab. If this clinic is not convenient to you please call us at 1-800-367-0677

- The Baltimore facility can only receive walk-in appointments Monday, Tuesday and Thursday between 8AM and 3 PM.
- **Please do not give blood on Friday or the day before a holiday**

IF you have a doctor's appointment at the VA where blood will be requested:

- First go to your doctor's appointment.
- When blood is requested give the envelope to the attendant.
- Blood will be drawn for your doctor and for our project at the same time.
- Even if you have an appointment please do not give blood for our study on Friday or the day before a holiday.

IF you do not have an appointment at the VA, or blood is not requested at your appointment. Go directly to the Blood drawing area in the VA and give the attendant this envelope.

Directions to the blood drawing area at Baltimore:

- The blood drawing area is located in 1C179 in the primary care area.

THANK YOU FOR SUPPORTING OUR PROSTATE DISEASE PROJECT



43006

**MAVERIC PHLEBOTOMY TEST
PROSTATE CANCER STUDY
PATIENT INFORMATION FORM**

White Styrofoam kits are stored in the lab with instructions to draw three 10ml EDTA tubes for MAVERIC Research. Please fill out the following information about the participant and FedEx this form along with the bloods to the MAVERIC Core Blood Lab.

MAV-W2

Participant ID: _____

VAMC Station Number: _____

Date of Draw: _____ / _____ / _____

Time of Draw: _____ : _____ Hours

Time since last meal: Less than 8 hours
(Please check one) 8-12 Hours
 12-16 Hours
 More than 16 hours

THANK YOU FOR SUPPORTING OUR PROSTATE DISEASE PROJECT

VA Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ Date: _____

Title of Study: Risk Factors for Prostate Cancer Patterns**Principal Investigator: Dr. Douglas Bradham VAMC: Baltimore VAMC**

PURPOSE: The purpose of this research is to better understand the dietary, lifestyle, and genetic factors that may lead to prostate cancer. You have been selected because you have not been diagnosed with prostate cancer. In the blood collection part of the study, you are requested to donate blood on one occasion so that risk factors of prostate cancer can be studied. These tests will be performed at a later time and stored so that no person will be identified individually. This is a longitudinal study where patients are followed for many years and we do not yet know what specific tests will be performed.

PROCEDURES: Phlebotomy. A small needle will be passed into a vein in your arm and 30ml of blood will be removed (about 3 Tablespoons).

DISCOMFORTS and RISK: Placement of the needle in the arm causes mild discomfort. In most cases this will be the only inconvenience. Occasionally, a small amount of bleeding occurs beneath the skin causing a bluish mark, which lasts up to a week, and rarely becomes infected. The vein from which blood was drawn may develop a blood clot. Such a clot is not serious and requires no treatment.

BENEFITS: There are no known benefits to you from your participation in this study. You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others.

COSTS/COMPENSATION: You will not be paid for your participation.

CONFIDENTIALITY: If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. Your research records and medical records will be maintained according to this medical center's requirements. However, there is a possibility that the food and drug administration or the Information Review Board may inspect the records.

RESEARCH RESULTS: Your right to privacy will be respected in that all information gained from this study will be kept completely confidential. Blood specimens will be stored in our lab using blinded dummy identifiers. No person will be identified individually in any analysis or conclusions drawn. We will not provide individual information back to participants. Representatives from the U.S. Army Medical Research and Materiel Command (and, where applicable, the Food and Drug Administration) may inspect the records of the research in their duty to protect subjects in research. There will be no commercial applicability for the donated blood sample.

SUBJECT'S IDENTIFICATION (I.D. plate or give name - last, first, middle)



VA Department of Veterans Affairs

VA RESEARCH CONSENT FORM

(Continuation Page 2)

Subject Name: _____

Date: _____

Title of Study: Risk Factors for Prostate Cancer PatternsPrincipal Investigator Dr. Douglas Bradham VAMC: Baltimore VAMC

RIGHT TO WITHDRAW: Participation in this study is voluntary. You are not obligated to participate in this research. You are free to withdraw your consent at anytime. Refusal to participate will not affect your current or future medical care in any way at the VA Health Care System or the University of Maryland at Baltimore, University of Maryland Medical System.

UNIVERSITY STATEMENT: The University is committed to providing subjects of its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

The research described in this consent form has been classified as minimal risk by the University of Maryland Institutional Review Board (IRB), a group of scientists, physicians, and other experts. The Board's membership includes persons who are not affiliated with the University and persons who do not conduct research projects. The Board's decision that the research is minimal risk does not mean that the research is risk-free, however. Generally speaking, you are assuming the risks of research participation, as discussed in the consent form. But, if you are harmed as a result of the negligence of a research, you can make a claim for compensation. If you believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact the IRB for more information about claims procedures.

Institutional Review Board
 University of Maryland
 655 West Baltimore Street, #BRB-14-016
 Baltimore, Maryland 21201
 (410-706-5037)



VA Department of Veterans Affairs

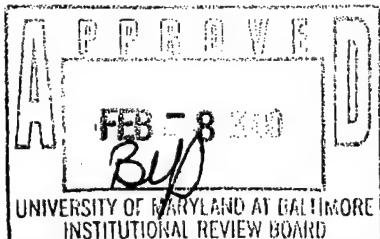
VA RESEARCH CONSENT FORM

(Continuation Page 3)

Subject Name: _____ Date: _____

Title of Study: Risk Factors for Prostate Cancer PatternsPrincipal Investigator Dr. Douglas Bradham VAMC: Baltimore VAMC

If you agree to join this study, please sign your name below.

NOT VALID WITHOUT THE
IRB STAMP OF CERTIFICATION

Subject's signature _____

 I have read and understand the information on this form. I have had the information on this form explained to me.VALID FROM 2-8-00 TO 2-7-01

Witness to Consent procedures* _____

RPN

NO.

1199028

Signature of Investigator _____

Date: _____

*Optional unless subject is illiterate or unable to sign.

NOTE: Copies of this Consent Form with original signatures **must be** a) retained on file by the Principal Investigator; and b) given to the subject. A copy must also be deposited in the patient's medical record (if any).

Appendix G



Face to Face Interview

49433

Subject ID: - -

Date: / / / / Time: : Military Time

Observed Race: African-American
 White

Survey was scheduled for later date:

Date: / / Time: : Military Time

How friendly was the conversation? **Very Friendly** **Hostile**
0.1 0.2 0.3 0.4 0.5

What was the level of distrust? 1 2 3 4 5

Survey results:

- Did not meet criteria
- Already enrolled
- Survey given
- Survey will be mailed by MAVERIC
- Unwilling to participate in face to face
- Completed face to face

SSN: - -

First Name

I. Last Name

Number & Street Address

City

State

Zip Code

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$$\boxed{} \quad \boxed{} \quad \boxed{} \quad \boxed{} \quad \boxed{} \quad - \quad \boxed{} \quad \boxed{} \quad \boxed{} \quad \boxed{}$$

(Area Code) Telephone Number

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49433

Subject ID:

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1) "Hi my name is _____ . I'm a Prostate Disease researcher with the VA Medical hospital. I am involved in a national study to look at dietary and lifestyle risk factors for prostate cancer. Would it be alright if I asked you a few questions while you are waiting; it will only take a few minutes..."

Yes "Thank You." continue...

No "Is this a bad time? Is there a better time?"

Yes → **Record date and time on front**

No → "Thank You for your time." → **STOP**

2) "Are you a U.S. Veteran?"

Yes → continue...

No → "Thank You for your time." → **STOP**

3) "Have you ever had cancer?"

No → continue...

Yes → "What type of cancer did you have?"

(type of cancer)

For any type other than skin cancer...

"This is all the information we need. Thank You." → **STOP**

4) "What is your date of birth?"

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If between 40 and 70 years old, continue...

else If younger than 40 (greater than 1960) or older than 70 (less than 1930): "This is all the information we need Thank you" → **STOP**

No → continue...

Yes → **Write participants name down on front**
Check list for name.

If name is on the list:

"This is all the information we need.
Thank you." → **STOP**

Yes → continue...

No → **Go to page 4**

OR

"Would you be willing to fill out this survey and mail it back to us later this week?"



49433

Subject ID:

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"In order for you to participate it is required that we document your willingness to participate in our study. This is a copy of our consent form, it explains our study, and your rights as a participant in our study. Please read these forms and sign the last page. If you have any concerns, or you need further explanation please let me know and I will answer your questions to the best of my knowledge."

(Show participant survey consent form)

7) "Did you have any difficulty reading the form?"

No → continue to #8...

Yes, due to eyesight → "Will someone be available to help you read the survey?"

Yes → continue...

No → "We appreciate your interest in being part of our study, however the survey may be difficult for you to read. Thank you for very much for your time." → **STOP**

8) Did the participant sign the consent form?

No, refused → **Go to page 4**

Yes → Continue...

Collect participants name, address, SSN, and phone number (first page). Tell the participant:

9) "Would you be willing to provide a blood sample for our research? Your blood sample will help us to identify important risk factors for prostate cancer."

No, refused → **Go to end statement at the bottom of the page.**

Yes

"We appreciate your participation in our prostate cancer project. The results will help our efforts to prevent and treat prostate cancer."

STOP



49433

Subject ID:

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"I respect your wish not to participate in this study, another important aspect of our study is to collect reasons for nonparticipation in these types of studies."

10) *"Would you be willing to share with us some of the reasons you choose not to participate?"*

Yes → Ask participant to sign the "Reasons for Non-Participation Consent Form" **Write the name and last 4 of the SSN on the front page.** Continue to #10...

No → "Thank you." → **STOP**

11) Are you concerned about the confidentiality of your responses?

Yes

Comments

12) *"Would you have been willing to participate if the survey was offered in a personal face to face interview?"*

Yes

13) *"Does your past experience with the VA health care influence your decision not to complete these questionnaires?"*

Yes

14) *"Do you choose not to participate in any research projects?"*

Yes

15) *"Have you participated in VA research projects including completing surveys in the past?"*

Yes

IF YES, "Have you had good or bad experiences participating in research projects?"

GOOD

BAD

NO OPINION

16) *"Do you think medical research helps veterans get better care?"*

Yes

No

17) *"Do you think prostate cancer is an important health care issue?"*

YES

NO

DONT KNOW

Subject ID:

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18) "Would you mind identifying the highest level of education you have completed?"

List catagories to participant:

- Grade School
- High School
- Trade School
- 2 year college
- 4 year college
- Graduate/professional school
- Participant refused to identify education

If African-American:

19a) "Is prostate cancer a serious problem for the African-American community?"

 YES**Comments** NO DONT KNOW

19b) "Do you think research on prostate cancer helps African Americans?"

 YES NO DONT KNOW

"From past studies it has become apparent that African Americans choose not to participate more often than white Americans. Is there something that we could change in our approach that would encourage more African Americans to participate in Scientific Research?"

*"Thank you for participating.
This information will be helpful to future health care studies.
Thanks again. Goodbye"*

STOP



MAVERIC

MASSACHUSETTS VETERANS EPIDEMIOLOGY
RESEARCH AND INFORMATION CENTER



Harvard



Medical School
School of Public Health

Boston University



School of Medicine
School of Public Health

August 1, 2001

«First_N» «Last_N»

«Address»

«CITY», «STATE» «ZIP»

Dear MR. «Last_N»,

It was a pleasure meeting you the other day in the outpatient clinic of the Baltimore VA Medical Center. Thank you for enrolling in the research study: "Risk Factors for Prostate Cancer." As discussed, I have enclosed a lifestyle and a dietary survey for you to complete and return in the enclosed envelope. It is possible that you may be contacted to complete additional questionnaires in the future. Completion of these questionnaires is completely voluntary. Please feel free to contact us at the Prostate Cancer Center phone line (1-800-367-0677) if you have any questions about this study.

This is a scientific study which is being run nationally by the VA through the Massachusetts Veterans Epidemiological Research Information Center (MAVERIC.) Researchers at the Baltimore VAMC, Harvard University, Boston University, and the Department of Defense are working together with MAVERIC on this study. The VA Research Review Board has reviewed this study and supports its work.

We sincerely appreciate your interest in this prostate cancer study. Through the information provided by you, together we can learn more about the lifestyle and dietary behaviors contributing to the development of prostate cancer. Our hope is to eventually make better recommendations for the prevention of this disease.

Sincerely yours,

Leah Rathvon, MSPH
Project Coordinator, Baltimore VAMC

Steven Wright, Ph.D.
VA Boston Healthcare System

Douglas Bradham, DrPH
Baltimore VAMC



MAVERIC

MASSACHUSETTS VETERANS EPIDEMIOLOGY
RESEARCH AND INFORMATION CENTER



Harvard



Medical School
School of Public Health

Boston University



School of Medicine
School of Public Health

August 17, 2001

«First_N» «Last_N»

«Address»

«CITY», «STATE» «ZIP»

Dear MR. «Last_N»,

A couple of weeks ago we sent you questionnaires about your diet and lifestyle. Unfortunately we have not received any information back from you at this time. If you have already responded to our survey, please disregard this notice.

We hope that you are still interested in participating in this study. If so, please complete the enclosed questionnaires and return them in the enclosed envelope at this time. You may also be contacted to complete additional questionnaires in the future.

Please contact us at the Prostate Cancer Center phone line (1-800-367-0677) if you have decided not to participate or if you have some concerns about the study. We welcome your comments, as they are also an important part of this research.

Thank you again for your interest in this prostate cancer study. Through the information provided by you, together we can learn more about the lifestyle and dietary behaviors contributing to the development of prostate cancer. Our hope is to eventually make better recommendations for the prevention of this disease.

Sincerely yours,

Leah Rathvon, MSPH
Project Coordinator, Baltimore VAMC

Steven Wright, Ph.D.
VA Boston Healthcare System

Douglas Bradham, DrPH
Baltimore VAMC

Appendix H



1167

Phone Survey -version 1

Subject ID:

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3 week follow-up

Name: _____

Phone Number: _____

Observed Race: African-American
 WhiteDistribution Type: Mailed Hand-out

Recruitment Date: _____

First Attempt:Date:

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 Time:

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 Military TimeResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

Second Attempt:Date:

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 Time:

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 Military TimeResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

Third Attempt:Date:

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 Time:

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 Military TimeResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

1. Successful Interview, recalls survey
2. Doesn't Recall/ did not receive survey
3. Unwilling to Participate
4. Unable to Participate due to health reasons
5. No Answer/ busy
6. Left message
7. Wrong Number
8. Phone Disconnected
9. Other (describe in comment)
10. ~~Prostate Cancer~~
11. Completed Survey



1167

Subject ID:

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"Hi this is _____. I'm a (nurse, health researcher, other) with the Prostate Disease Project at the Baltimore VA Medical Center."

"May I speak with Mr. _____. "

If not home, ask for a time that is good for the participant _____.
Repeat introductory phrase if participant is called to the phone. Otherwise continue ...

"Leah met you a few weeks ago at the Baltimore VA. At the time you agreed to fill out a some surveys for us. We recently sent you a package with two questionnaires. The questionnaires asked about your diet, physical activity, medication use, and smoking."

1) "Did you receive these questionnaires?" (Describe questionnaires to participant if they can't recall: "The questionnaires were initially sent in _____ in a large manila envelope. One questionnaire was green the other was pink. A second copy was sent over a week ago."

Yes

→ If YES, Go to question 4

No

→ If NO, "Can I verify your address?"

2) Check participant's address:

OLD:

NEW:

Has the address changed?

No

→ If NO, Go to question 4

Yes

→ IF YES,

3) "Would you be willing to complete these questionnaires if we sent you a copy to your new address?"



No

→ If NO, Go to question 4

Yes

→ IF YES, Mail survey...

"We appreciate your participation in our prostate cancer project. The results will help our efforts to prevent and treat prostate cancer."





1167

Subject ID:

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4) "We are trying to learn the best way we can collect this information. It's helpful to know why people did not respond so we can improve our survey. Can we ask you a few questions about why you did not respond? It should take about ten minutes."

No → **IF NO**, "Is this a bad time? Is there a better time we can call?" _____
If participant is unwilling to participate - "Thank You for your time. Goodbye."



Yes → **IF YES**, "Thank You." continue...

If participant did not receive the surveys then skip to the next page

5) "Did you have difficulties understanding the cover letter or instruction sheet?" Yes No

6) "Did the questionnaires look too long?" Yes No

7) "Did you have difficulties understanding the questions in the survey?" Yes No

8) "Did you not have time to complete the questionnaires?" Yes No

9) "Did you not feel well enough to answer the questions?" Yes No

10) "Did you feel there were too many questions to answer?" Yes No

11) "Did you have difficulties recalling details asked in the questions? For example did you have difficulties recalling your diet, medical treatments, vitamin use, PSA levels?" Yes No

12) "Were you concerned about the confidentiality of your responses?" Yes No

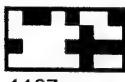
13) "Did you find the questions too sensitive to answer?" Yes No

14) "Did past experience with the VA influence your decision to complete these questionnaires?" Yes No

15) "Do you choose not to participate in any research projects?" Yes No

16) "Do you wish to share with us any other reasons for not completing the questionnaires?" Yes No

Participants may spend a lot of time with this question. If so, redirect them to the next set of questions.



1167

Subject ID:

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17) "Do you receive your usual care from the VA?" Yes No18) "Have you had positive experiences with the health care that you've received from the VA in the past 3 months?" Yes NoComments: _____

19) "Have you participated in VA research projects including completing surveys in the past?"

 No Yes → **IF YES,**

"Have you had good or bad experiences participating in research projects?"

 GOOD BAD NO OPINIONComments: _____

_____20) "Do you think medical research helps veterans get better care?" Yes No21) "Do you think prostate cancer is an important health care issue?"
 YES
 NO
 DON'T KNOW

22) "Would you mind identifying the highest level of education you have completed?"

(List categories to the participants) →

- Grade School
- High School
- Trade School
- 2 year college
- 4 year college
- Graduate/professional school
- Participant refused to identify education

Subject ID:

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23) If African-American (see front page) then complete a and b below:

a) "Is prostate cancer a serious problem for the African-American community?"

YES NO DON'T KNOW

b) "Do you think research on prostate cancer helps African Americans?"

YES NO DON'T KNOW

If the participant received the survey then skip to the last question (#26)

24) "If you had received the survey, would you have completed it?"

Yes No

25) "Would you have been willing to participate if the survey was offered over the telephone?"

Yes No

26) "Would you have been willing to participate if the surveys were administered in a face to face interview with a researcher at the hospital?"

Yes No

"Thank you for participating.
This information will be helpful to future health care studies.

Thanks again
Goodbye"





870

Phone Survey -version 2

Subject ID:

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2 week follow-up

Name: _____

Phone Number: _____

Observed Race: African-American
 WhiteDistribution Type: Mailed Hand-out

Recruitment Date: _____

First Attempt:Date:

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Time:

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 Military TimeResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

Second Attempt:Date:

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Time:

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 Military TimeResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

Third Attempt:Date:

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Time:

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 Military TimeResponse: 1 2 3 4 5 6 7 8 9 10 11

Comment: _____

1. Successful Interview
2. ~~Doesn't Recall/ did not receive survey~~
3. Unwilling to Participate
4. Unable to Participate due to health reasons
5. No Answer/ busy
6. Left message
7. Wrong Number
8. Phone Disconnected
9. Other (describe in comment)
10. ~~Prostate Cancer~~
11. Completed Survey



870

Subject ID:

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"Hi this is _____. I'm a (nurse, health researcher, other) with the Prostate Disease Project at the Baltimore VA Medical Center."

"May I speak with Mr. ____"

If not home, ask for a time that is good for the participant _____

Repeat introductory phrase if participant is called to the phone. Otherwise continue ...

"Leah met you a few weeks ago at the Baltimore VA. At the time you agreed to fill out a some surveys for us. The questionnaires asked about your diet, physical activity, medication use, and smoking. One of the surveys was green the other was red with an apple on it."

1) "We are trying to learn the best way we can collect this information. It's helpful to know why people did not respond so we can improve our survey. Can we ask you a few questions about why you did not respond? It should take about ten minutes."

No → **IF NO,** "Is this a bad time? Is there a better time we can call?" _____

If participant is unwilling to participate
- "Thank You for your time. Goodbye."



Yes → **IF YES,** "Thank You." continue to the next page..

Subject ID:

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2) "Did you have difficulties understanding the cover letter or instruction sheet?"

Yes No

3) "Did the questionnaires look too long?"

Yes No

4) "Did you have difficulties understanding the questions in the survey?"

Yes No

5) "Did you not have time to complete the questionnaires?"

Yes No

6) "Did you not feel well enough to answer the questions?"

Yes No

7) "Did you feel there were too many questions to answer?"

Yes No

8) "Did you have difficulties recalling details asked in the questions?"

For example did you have difficulties recalling your diet,
medical treatments, vitamin use, PSA levels?"

Yes No

9) "Were you concerned about the confidentiality of your responses?"

Yes No

10) "Did you find the questions too sensitive to answer?"

Yes No

11) "Did past experience with the VA influence your decision to complete these questionnaires?"

Yes No

12) "Do you choose not to participate in any research projects?"

Yes No

13) "Do you wish to share with us any other reasons for not completing the questionnaires?"

Yes No

Subject ID:

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14) "Do you receive your usual care from the VA?" Yes No

15) "Have you had positive experiences with the health care that you've received from the VA in the past 3 months?" Yes No

Comments: _____

16) "Have you participated in VA research projects including completing surveys in the past?"

No

Yes → IF YES, "Have you had good or bad experiences participating in research projects?"

GOOD BAD NO OPINION

Comments: _____

17) "Do you think medical research helps veterans get better care?"

Yes No

18) "Do you think prostate cancer is an important health care issue?"

YES NO DON'T KNOW

19) "Would you mind identifying the highest level of education you have completed?"

(List categories to the participants) →

- Grade School
- High School
- Trade School
- 2 year college
- 4 year college
- Graduate/professional school
- Participant refused to identify education

20) If African-American (see front page) ask a and b:

a) "Is prostate cancer a serious problem for the African-American community?"

YES NO DON'T KNOW

b) "Do you think research on prostate cancer helps African Americans?"

YES NO DON'T KNOW

21) "Would you have been willing to participate if the surveys were administered in a face to face interview with a researcher at the hospital?"

Yes No

"Thank you for participating. This information will be helpful to future health care studies.
Thanks again. Goodbye"